Managing Potentially Toxic Substances in Canada

National Round Table
on the Environment
and the Economy

Table ronde nationale
sur l'environnement
et l'économie

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National Round Table on the Environment and the Economy
344 Slater Street, Suite 200
Ottawa, Ontario
Canada K1R 7Y3
Tel.: (613) 992-7189
Fax: (613) 992-7385
E-mail: admin@nrtee-trnee.ca
Web: http://www.nrtee-trnee.ca

Managing Potentially Toxic Substances in Canada

A State of the Debate Report from the National Round Table on the Environment and the Economy

The National Round Table on the Environment and the Economy (NRTEE) was created to "play the role of catalyst in identifying, explaining and promoting, in all sectors of Canadian society and in all regions of Canada, principles and practices of sustainable development." Specifically, the agency identifies issues that have both environmental and economic implications, explores these implications, and attempts to identify actions that will balance economic prosperity with environmental preservation.

At the heart of the NRTEE's work is a commitment to improve the quality of economic and environmental policy development by providing decision makers with the information they need to make reasoned choices on a sustainable future for Canada. The agency seeks to carry out its mandate by:

- advising decision makers and opinion leaders on the best way to integrate environmental and economic considerations into decision making;
- actively seeking input from stakeholders with a vested interest in any particular issue and providing a neutral meeting ground where they can work to resolve issues and overcome barriers to sustainable development;
- analysing environmental and economic facts to identify changes that will enhance sustainability in Canada; and
- using the products of research, analysis and national consultation to come to a conclusion on the state of the debate on the environment and the economy.

The NRTEE's state of the debate reports synthesize the results of stakeholder consultations on potential opportunities for sustainable development. They summarize the extent of consensus and reasons for disagreement, review the consequences of action or inaction, and recommend steps specific stakeholders can take to promote sustainability.

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The NRTEE is composed of a Chair and up to 24 distinguished Canadians. These individuals are appointed by the Prime Minister as opinion leaders representing a variety of regions and sectors of Canadian society including business, labour, academia, environmental organizations, and First Nations. Members of the NRTEE meet as a round table four times a year to review and discuss the ongoing work of the agency, set priorities, and initiate new activities.

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Foreword

The National Round Table on the Environment and the Economy (NRTEE) established its program on Health, Environment and the Economy to investigate how government assesses chemical substances and how it makes decisions about their use. The program included the examination of four case studies, and consultation with stakeholders.

As Chair of the NRTEE, I am pleased to introduce this report, which presents 11 recommendations aimed at improving the decision making that protects Canadians from dangerous chemicals in air, water, soil and food.

Stuart L. Smith, M.D.
Chair, NRTEE

1

Introduction

Canadians are increasingly concerned about the health impacts of chemical substances in the environment. Yet they still want the economic benefits of new chemicals, materials and medicines.

In 1998, the National Round Table on the Environment and the Economy (NRTEE) began a multistakeholder process to investigate how government assesses chemical substances and how it makes decisions about their use. This report documents the results of that work, presenting 11 recommendations aimed at improving the decision-making processes designed to protect Canadians from health impacts that could result from contact with dangerous chemicals in air, water, soil and food.

A key finding of the report, based on strong stakeholder input, is that many problems in the decision-making process stem from reduced government capacity to assess substances. Compounding the impacts of funding cuts are advances in scientific understanding of how substances in the environment affect human health. These developments often point to the need for more complex—and hence more resource-intensive—assessment procedures.

For example, while cancer has historically been the focus of assessments, recent research suggests that significant, non-cancer health impacts can arise from long-term, low-level exposure to a mix of substances. Governments are therefore trying to determine whether the current scope of their research and regulatory activities is appropriate.

This report also highlights the need to increase public confidence in the regulatory process by encouraging greater government openness and public involvement.

How the work was carried out

To study government decision-making processes, the NRTEE created a Task Force on Health, Environment and the Economy that included members of the NRTEE and a variety of experts and stakeholders. The work proceeded as follows:

First, the Task Force conducted four case studies into how the government made decisions with respect to four chemical substances. It then analysed these studies.

Second, the Task Force shared the results of the case-study analysis at a stakeholder workshop held in January 2000. The participants, who were drawn from across Canada, were urged to be frank about their differences.

Third, the Task Force examined the experiences of other jurisdictions.

Finally, the Task Force and all NRTEE members debated and approved specific recommendations for change in the way government makes decisions about potentially hazardous substances and their use.

Commissioner documents reduced resources

A few weeks after the NRTEE decided to focus on government decision making, the Commissioner of the Environment and Sustainable Development (the Environment Commissioner) released his annual report. Part of it reviewed an audit of the way government handles toxic substances and concluded that there was "a growing gap between the demands placed on [federal] departments to provide scientific information on toxic substances and their ability to meet existing obligations and respond to emerging issues."[1]

The Commissioner also noted that reassessment of existing substances falling under the *Canadian Environmental Protection Act* and the *Pest Control Products Act* lagged far behind their mandated schedule. "Within existing budgets," he said, "departments are struggling to meet legislated responsibilities, policy commitments and international treaty obligations and, in many cases, are failing to do so."[2]

Between 1994 and 1998, four science-based departments—Environment Canada, Fisheries and Oceans Canada, Health Canada and Natural Resources Canada—reduced their personnel by 17 percent.[3] The negative repercussions of these cuts were clearly expressed by scientists interviewed by the Commissioner,[4] as well as by stakeholders consulted by the NRTEE in the months before and after the Commissioner's report was released.

Four real-life case studies

As mentioned, the NRTEE Task Force used a case-study approach to examine decision-making processes surrounding substance assessment and management. This approach enabled the Task Force to focus on real-life situations rather than theoretical frameworks.

Recognizing that it is difficult for four case studies to cover the full spectrum of decision-making processes, the Task Force took care to choose representative substances that would provide broad insights into how government typically makes decisions about potentially hazardous substances.

Lindane. Registered in Canada 60 years ago, this pesticide has been identified as a persistent organic pollutant (POP) and found in significant levels in northern peoples. This case study examined the regulatory responses to the identification of lindane as a POP and to the U.S. policy of preventing the importation from Canada of canola seed treated with lindane.

The case study also looked at the stakeholder issues surrounding the negotiation of Canada's international position on the use of lindane. It revealed how stakeholders both outside and inside government (particularly Aboriginal groups) were frustrated at being unable to obtain the risk and health assessment data used to determine lindane's safety. (Because of its proprietary nature, this information was exempted from public release under the *Access to Information Act*.)

Sulphur in gasoline. This case study explored how new regulations for sulphur levels in gasoline were developed through the use of an expert panel and extensive stakeholder participation. While this process did not run completely smoothly, it demonstrated that third-party input can contribute to concrete policies where the science is complex and controversial. This case study illustrated a decision-making process that attempted to ensure its own transparency and access to relevant data.

MMT. The MMT case study compared the American and Canadian procedures used to determine the management of this octane-enhancing fuel additive. Part of the case study focused on the Canadian government's decision to use trade legislation to control the use of MMT. The study documents how this decision was made without the use of a clear-cut process and without informing stakeholders about how the decision was made or how information was used.

Revalor-H. This case study investigated the approval process for the Revalor-H beef growth promoter, as well as communication issues linked to the veterinary drugs approvals process. It also examined the dispute between the European Union and Canada over six other beef growth promoters used by the beef industry in North America. The approval of veterinary drugs such as Revalor-H is regulated by a well-defined process, but once again outsiders found it difficult to get basic information on the status of the drugs under review. The information used for the assessment was practically inaccessible to those outside the decision-making process.

How the current regulatory system works

Nine pieces of federal legislation apply to toxic substances in Canada. New and existing substances are primarily regulated by the *Canadian Environmental Protection Act* (CEPA), the *Food and Drugs Act* (FDA), the *Pest Control Products Act* (PCPA), the *Hazardous Products Act*, the *Fertilizers Act*, the *Fisheries Act* and the *Feeds Act*.

Enacted in 1988, revised in 1999, and administered jointly by Environment Canada and Health Canada, CEPA deals with toxic substances not regulated under any other piece of federal legislation. The approach the government uses under the current version of CEPA sets out two tracks for the management of toxic substances:

- virtual elimination from the environment of toxic substances that result from human activity and that are persistent and bio-accumulative;

- management of other toxic substances of concern, during their life cycles, to prevent or minimize their release into the environment.

The tools to manage toxic substances under CEPA now include pollution prevention plans, environmental emergency plans, virtual elimination plans, regulations, economic instruments, guidelines, objectives, and codes of practice.

The sulphur in gasoline case study featured the development of a regulatory measure (the Sulphur in Gasoline Regulation) under CEPA.

The PCPA regulates the registration of all products imported, manufactured, sold or used in Canada to control pests. It states that no pest control product will be registered until all associated health or environment health risks have been deemed acceptable and the product has been shown to serve a useful purpose.

However, the extent of testing and verifying of these products, especially in regard to vulnerable populations and long-term exposures, is the subject of considerable debate. The processes that governed lindane's management were initiated through the PCPA, an act that is currently being revised.

The FDA applies to all food, drugs, cosmetics and medical devices sold in Canada, whether manufactured in Canada or imported. New drugs cannot be marketed in Canada without approval from Health Canada confirming that their manufacture and sale comply with FDA regulations, which specify safety, compositional, nutritional and labelling requirements.

In addition to showcasing the decision-making processes associated with different pieces of legislation, the four case studies also helped illuminate issues surrounding the regulation of existing and new synthetic substances and naturally occurring substances. For instance, the lindane and MMT case studies reviewed situations where approval for use in Canada had already been granted but where there was pressure to reconsider the initial approval. The Revalor-H case study looked at the approval of a new veterinary drug, and the sulphur in gasoline case study focused on the regulation of a naturally occurring substance that can be transformed into several different types of pollutants when gasoline is burned.

It is important to note that Canada's legislative framework for assessing and managing substances is changing. CEPA underwent major amendments in 1999 (referred to as "CEPA99" throughout this report). Meanwhile, upcoming amendments to the PCPA may change practices related to the assessment and registration of pesticides. Many of these existing and future amendments are directly linked to issues such as the transparency or integration of decision-making processes.

The Health Protection Branch of Health Canada is also upgrading its infrastructure to support stronger management of toxic substances. Its goal is to make better use of cutting-edge science and new information technologies, and to streamline legislation.

Stakeholders express clear concerns

On January 13 and 14, 2000, the NRTEE hosted a multistakeholder workshop on health and environmental policy processes in Canada. The 70 workshop participants represented a broad range of governmental, industry and environmental organizations. Rather than "paper over big gaps with wordsmithing," participants were urged to be frank about areas where they disagreed to help Canadians understand genuine differences. Despite their widely varying backgrounds, the majority of participants agreed that they wanted decision-making processes that would:

- be more open and transparent;
- be somewhat standardized and predictable for all participants;
- include better communication across government and with the general public;

- be based on greater scientific capacity in government so as to provide balanced, credible input to policy- and decision-making processes.

Participants pointed to several key areas for change based on the case studies and discussion:

1. integration of health and environmental issues;
2. capacity for creating, processing and managing scientific information;
3. transparency of decision making.

Starting from these areas of convergence, the NRTEE identified specific recommendations to improve health and environmental decision-making processes. These recommendations are set out at the end of this report.

Integrating health and environmental issues

On the basis of the four case studies, workshop participants identified a consistent and serious lack of integration of health and environmental issues in policy making.

The studies showed how the policies of one department could contradict the findings of another, as seemed to be the case for MMT. Another case study demonstrated how one branch of government could identify potential dangers of a persistent organic pollutant like lindane yet fail to trigger an immediate response by the responsible regulatory agency.

The Environment Commissioner's 1999 report (referred to above) had also detected tensions within various government departments and warned of a "silo" effect—that is, departments and agencies viewing issues from their perspective alone.

In contrast to Canada, the United States has a more centralized system. The U.S. Environmental Protection Agency (EPA), for example, is mandated to act as a watchdog for both the environment and human health. The U.S. system embraces independent institutions such as the National Academy of Sciences, the highly regarded Atlanta Toxic Substances Disease Registry, a "superfund" to clean up environmental disasters and programs to evaluate the impact of environmental factors on children's health.

Addressing horizontal issues

The silo effect noted in the Environment Commissioner's report makes it difficult for government to address issues that cut across disciplinary boundaries and departmental mandates. Environment ministers from the G7 countries, plus Russia, signed a *Declaration on Children's Environmental Health* in May 1997. The declaration acknowledged the need to consider the special physiological and social needs of children in order to protect them from hazards such as air pollution, lead exposure, unsafe drinking water and tobacco smoke.

Health Canada and Environment Canada have since investigated their risk-assessment/management plans and pinpointed areas needing attention. Better collaboration among federal departments on children's environmental health was the topic of a recent interdepartmental meeting in Ottawa. However, a lack of resources has hindered progress on the children's environmental health agenda across the departments participating in the interdepartmental initiative. As a result, efforts to better address the unique vulnerabilities of children to environmental hazards (e.g., substance assessment and management) may require additional resources before significant progress is realized.

Harmonizing assessments

The need for more scientific capacity was a recurring theme raised by the four case studies and the workshop participants. Participants pointed to delays in conducting regular reassessments of substances on CEPA's Domestic Substances List and pesticides already registered under the PCPA.

One solution to the assessment backlog is for Canada to do more harmonizing with other countries. The Organization for Economic Cooperation and Development (OECD) is undertaking several joint efforts to foster the mutual acceptance of data related to the assessment of chemicals. For example, all OECD member countries, including Canada, have agreed to accept safety data developed in other member countries to support the risk assessment process. As well, there is a series of OECD initiatives dealing with registration, notification, cooperative assessments, and assessment and classification of best practices addressing new and existing chemicals and pesticides. These efforts will determine the extent to which countries will accept other nations' assessment information and, potentially, their regulatory decisions. With regard to the assessments of veterinary drugs such as Revalor-H, the Office international des epizooties (OIE) is also initiating a drug harmonization process.

While these harmonization initiatives will not remove a country's authority to approve or reject a substance, it is hoped that increased efficiencies will reduce costs for businesses and governments.

Canada is working with the U.S. EPA to assess high-volume chemicals. Another Canada-U.S. initiative, the Four Corners pilot project, will experiment with increased data sharing between both countries to speed up evaluation of new substances. CEPA99 also includes provisions that require Canada to cooperate with other OECD countries to exchange information on prohibited or severely restricted substances, or to re-examine any substance that an OECD country decides to prohibit for environmental or health reasons.

Despite these commendable efforts of governments to work together, stakeholders stressed that worthwhile progress still depends on adequate government funding. For example, concerns were raised that while CEPA99 will permit joint work with other jurisdictions, no resources have yet been allocated. Moreover, although the OECD is developing a protocol to assess endocrine disrupters, this important work will only advance if stable program funding is provided to allow long-term research strategies to be developed and expert staff to be retained. A lack of funding could prevent Canada from including the resulting data from these harmonization initiatives in its national decision making.

Need for greater capacity to create and manage scientific information

The second and perhaps most strongly supported theme to emerge from the four case studies was government's reduced ability to generate and manage scientific data that support policy development. There is a clear need to increase research capacity outside government and knowledge management inside government.

Our government is routinely asked to make decisions that must weigh public health, environmental and commercial interests. Science plays a crucial role in these decisions but one that is increasingly difficult because of budget constraints, rising public expectations, globalization, increasing complexity of science and new technologies.

[illegible] that is increasingly difficult because of budget constraints, rising public expectations, globalization, increasing complexity of science and new technologies.

Need for increased research

Stakeholders expressed significant support for the creation of greater capacity to conduct environmental health research. The prevailing view suggested that research on health and environment be coordinated through the new Canadian Institutes of Health Research (CIHR). Ties to major North American academic centres would allow for greater collaboration in complex and expensive fields of research. Multidisciplinary and cross-disciplinary representation was also considered essential, given the breadth of the issues.

Re-evaluating existing substances

The case studies illustrated the lack of policy mechanisms for revisiting existing substances when new information emerges. This was evident in the lindane case study, which featured a substance registered decades ago and recently identified as a persistent organic pollutant.

The Environment Commissioner's 1999 report noted that the Pest Management Regulatory Agency (PMRA) had not allocated any funds for a systematic re-evaluation of existing pesticides at the time of the study. The report also noted that the U.S. program spends 25 percent *more* on re-evaluating pesticides than on registering new ones.[5] Although the PMRA has since received an additional $7 million allocated over two years, that will not raise its budget to comparable U.S. levels.

New information should require reconsideration of earlier decisions about approvals, standards or thresholds. CEPA99 addresses the issue of new data, making registrants responsible for submitting significant new data on substances already in use. These new data could then trigger a reassessment. This clause, however, pertains only to information from business proponents and not to that from *all* sources.

Handling scientific uncertainty

The MMT and sulphur in gasoline cases were characterized by scientific issues that were hotly disputed by the petroleum and automotive industries. In the sulphur case, the policy implications of the current state of the science were assessed by a group that all major stakeholders found credible; this assessment was then used in developing new regulations. The MMT decision-making process, in contrast, had no equivalent mechanism for addressing contentious issues.

The case studies pointed to the need to increase the ability of government to call on outside help in reviewing data from diverse sources. Stakeholders agreed that third-party input could be effective in moving the debate forward when there is scientific uncertainty. The Royal Society of Canada and the U.S. National Academy of Sciences sometimes receive funding for convening panel processes that operate independently from the funding agency. The panels are made up of multidisciplinary experts, which increases the likelihood of reaching impartial decisions. Other resources could include universities, businesses and non-governmental organizations. Expert panels represent an accepted means of resolving conflict in interpreting data.

It was also suggested that one way to handle inadequate information or scientific uncertainty would be to grant conditional approval only when the benefits to society are potentially great and any concerns minor. This type of conditional approval is sometimes given to the experimental or controlled use of new drugs.

Conditions for such approval would include:

- early re-review;
- limited application;
- special care in the use and disposition of the product.

Transparency in decision making

The third theme identified by workshop participants was government's lack of transparency—in particular, its failure to communicate clearly, candidly and regularly, to stakeholders and the public, the government's standards and procedures for deciding which substances to approve, reject or manage (as in the case of the regulation of a pollutant).

The four case studies documented how some representatives of both industry and environmental groups were unable to access needed information or were frustrated in their attempts. In several instances, they were left in the dark about the process; they were unsure about what was being assessed, when the assessment would take place, or who would participate. Often, it was difficult to gain access to data on substances.

Stakeholders considered the ongoing dissemination of clear and concise information an essential first step in increasing transparency. Basic information on all substance approvals should be routinely available—not just when requested.

Stakeholders considered the ongoing dissemination of clear and concise information an essential first step in increasing transparency.

More information is becoming available. Part of the 1999 amendments to CEPA included a provision for an Environmental Registry. The recently launched Registry acts as a source of public information on activities under CEPA. As well as providing up-to-date copies of current CEPA instruments, the Registry will also help the public to monitor proposed regulations and orders and public consultations.

Other important initiatives include Health Canada's recently completed *Health Canada Decision Making Framework for Identifying, Assessing and Managing Risks to Human Health.* This framework incorporates requirements for engaging the public at every stage of decision making from the identification of the issue through to assessment, public intervention and follow-up monitoring activities. Also, the mandate of Health Canada's new Office of Consumer Affairs and Public Involvement is to increase the department's capacity to engage the public on a range of health issues, including those related to environmental hazards.

The NRTEE believes that all departments and agencies should follow established processes when deciding whether to approve the use of new chemical substances and whether to remove or restrict the use of existing chemical substances. The public should have easy access to information on the stages of the process, on what substances are currently under review, and on what stage a particular substance has reached in the assessment process.

Examples of successful communication

A review of existing process communication tools suggested that governments are progressing in this area. For example:

- The Ontario Environmental Bill of Rights oversees an electronic database—the Environmental Registry—that anyone can access via the Internet. Certain ministries must include proposals on this Web site for environmentally significant instruments such as permits and licences. However, some users have found the information unclear, incomplete or hard to find.
- The Canadian Council of Ministers of the Environment (CCME) boasts a progressive example of public communication in its Canada-wide Standards process. The public can find a complete timetable for the development of these standards on the CCME Web site, which includes dates for each step and stages where public input is invited. All substances under review are listed and a generic template for the standard development process is available. Interested parties can even register to receive e-mail notice of new developments.
- The federal Regulatory Process Management Standards (RPMS) provide the basis for a generic template that could enable more consistency within and across departments and agencies. Created as a regulatory reform tool and implemented in the mid-1990s, the RPMS use a standardized process to describe the key steps in formulating regulations that all federal regulatory departments follow when developing regulations.
- The Canadian Centre for Management Development is considering putting all process

information under one roof to make it easier to navigate the current maze:

> *Citizens want government services that are as accessible, convenient and seamless as possible. One way is through single-window service delivery…the bringing together of government services, or information about them, in order to reduce the amount of time and effort citizens must expend to find and obtain the services they need.*[6]

Release proprietary information when appropriate

Some of the information that business supplies to government as part of the substance review process is not shared with the public, or with other government departments. This lack of information sharing is based on a provision of the Canadian *Access to Information Act*, which allows heads of federal departments (and agencies) to restrict access to information that could pose a risk to their departments. The Act gives departmental officials a certain amount of discretion in determining what information should be deemed "sensitive," and proprietary information frequently falls into this category. For instance, stakeholders felt that far too much outdated material is needlessly treated in a confidential manner.

To alleviate this problem, guidelines for public servants could encourage more openness with the public and between departments while still restricting the distribution of legitimate proprietary information. Part of the answer may lie in more clearly defining when third-party information may or may not be accessed.

It should be noted that in February 2000 Health Minister Allan Rock announced plans to amend the *Pest Control Products Act* to the House of Commons' Standing Committee on Environment and Sustainable Development:

> *The new statute will permit the public to inspect health and environmental test data supporting pesticide registrations, so we'll be providing Canadians with a way to satisfy themselves that those risk assessments are comprehensive… [S]ubject only to legitimate proprietary interest concerns…, [the intention will be] to tell the public as much as we can about the products so that they can form their own view.*[7]

In conclusion

The NRTEE's program on substance assessment and management in Canada used research, retrospective case studies and multistakeholder input to conclude that:

- There is a widely perceived need to improve the decision-making process surrounding substance assessment and management in Canada.
- Health and environmental factors must be better integrated into the process.
- Resources are insufficient for the task ahead. The capacity to create and evaluate scientific information must be substantially increased.
- Decision making must be more open with clearer, faster communication.
- Government should reassess existing substances—not just new ones.

2

Final Recommendations

The NRTEE's program on Health, Environment and the Economy addressed the full range of governmental activities that involve decision making linked to the assessment and management of substances.

Final Recommendations

Note on the recommendations: The NRTEE's program on Health, Environment and the Economy addressed the full range of governmental activities that involve decision making linked to the assessment and management of substances. In several cases, the ideas presented in these recommendations are already being implemented, in whole or in part, in some government departments and agencies. They are not, however, being implemented across the board; the NRTEE believes that there remain important gaps that should be addressed.

1A. The NRTEE recommends the creation of a federal government-wide Health and Environment Scientific Advisory Committee to support CEPA, the PCPA and other pieces of legislation that bear on the management of substances. This committee, which would comprise representatives from Environment Canada and Health Canada, would:

- report annually on the federal government's current capacity to carry out legislated activities;
- provide a research agenda to fulfil the legislated mandate more effectively;
- continuously review existing scientific information to identify emerging issues relevant to Canada's system for the management of substances;
- propose new research relevant to the Canadian situation;
- provide a coordinated response on those substances falling under the jurisdiction of several pieces of legislation.

The committee would report to both the Minister of Health and the Minister of the Environment.

1B. The NRTEE proposes that the Privy Council Office convene a meeting of deputy ministers twice a year to facilitate high-level commitment to the collaboration of federal departments on health and environmental issues.

2. The NRTEE recommends that the government provide $40 million over a period of three years to fund a strategic research initiative on health and environment within the existing Canadian Institutes of Health Research. The research initiative would:

- fund and link health and environment research within the CIHR's 13 institutes;
- create links with other jurisdictions such as the U.S. National Institute of Environmental Health, the U.S. National Academy of Sciences, provincial departments and academic centres;
- nurture the development of a multi-disciplinary and cross-disciplinary science base.

The research conducted by the Institutes might touch on occupational health, but this would not be a primary focus of its mandate.

3. Because the NRTEE believes that the Royal Society's independent expert panels can provide unbiased advice to augment decision making, it recommends that these bodies play an advisory role to government. The use of expert panels would be based on the following conditions:

- The decision to create a new panel should be based on criteria such as high cost impacts of the proposed policy and high degrees of scientific uncertainty.
- The panels should include multi-disciplinary and cross-disciplinary representation.
- The panels should focus on assessing the current state of scientific knowledge.

- Controversial scientific issues should be referred to the expert panel in a timely manner to better inform decision makers.

4. ***In order to address the growing challenges and complexities that government now faces when regulating substances, the NRTEE recommends drastically increasing government scientific capacity to:***

   - better judge the scientific material it receives, better perform or contract for its own scientific work where necessary, and take into account complex issues, such as those associated with taking children's health into account during substance assessment and regulation;
   - ensure timely reassessments of substances according to CEPA and the PCPA;
   - provide better access to data and processes relating to the decision-making processes in question.

5. ***The NRTEE recommends that the substance approval processes be expanded to allow conditions to be attached to the approval of a substance when a high degree of uncertainty is present. Such an approval would be possible only when the benefits to society are potentially great and the doubts, while insufficient to deny those benefits, are important enough to require:***

   - early review;
   - limited application;
   - special measures of care in the use and disposition of the product.

   A conditional approval would require a second review when additional data became available, or after a certain amount of time had elapsed, whichever came earlier.

6. ***The NRTEE recommends that systematic reassessments of existing substances take into consideration new scientific findings from all legitimate sources. New data are defined as data from legitimate sources that may influence an existing substance's status.***

7. ***The NRTEE recommends increasing the government's capacity to coordinate with other countries the task of reassessing existing substances, such as those falling under CEPA and the PCPA, and to jointly plan and share scientific data and assessments. Countries would follow a joint scientific protocol to leverage research programs and findings effectively. While the assessments would be shared, the final policy decision would remain with each national government.***

8. ***The NRTEE recommends that the federal government immediately increase interdepartmental action on the commitment Canada made at the May 1997 G8 Summit to consider the sensitivities, vulnerabilities and exposure patterns of children in all areas of environmental health and policy.***

9. ***The NRTEE recommends that the government make readily available clear information about the status of any substance it is evaluating. The government should communicate:***

   - a list of substances undergoing assessments;
   - what step a particular substance has reached within the process;
   - when and how the public can comment on the review and how this input will be used;
   - where the public can obtain additional information, including scientific data and the rationale for the decision, at the end of the process;
   - at the end of the evaluation, a summary of the scientific data and the rationale for the decision, including all references.

Public input would be sought at the last stage of the process, when appropriate.

To the extent possible, the government should develop common descriptions for the stages of an evaluation to avoid confusion and increase public understanding. Also, the Information Commissioner of Canada should review the efforts of departments and agencies to share this information in a clear and timely manner with the public, and should compel action if necessary.

10. The NRTEE recommends that the government increase public access to health and environmental information. The first category of information that should, wherever possible, be made more publicly accessible is the data submitted to government departments and agencies by third parties such as industry. The government should:

- communicate to the public whether this type of information may be accessed and whom to contact to obtain information that can be released;
- clarify the conditions under which the release of health and environmental information may affect the competitive position of a company (e.g., trade secrets);
- transfer third-party information between government departments and agencies when appropriate. In this situation, departments and agencies would have to identify key departmental representatives who, acting as information brokers, would be responsible for disseminating third-party information directly to relevant staff within other departments/agencies needing that information;
- develop department- and agency-specific guidelines for compliance with Access to Information legislation that encourage an interpretation of the statutes that is more consistent with the principle of openness;
- revise key legislation (CEPA, FDA, PCPA) to ensure public access to health and environmental data, subject only to legitimate proprietary interests;
- allow the distribution of third-party information if the information is outdated or if a change makes the need for restricting distribution to the public irrelevant;
- request that the Department of Justice provide the Information Commissioner of Canada with a mandate to evaluate the need for more open guidelines on interpreting the *Access to Information Act*.

A second category of information is information that is not exempted from distribution under the *Access to Information Act* but which is not easily accessible. Information falling into this category includes assessments of substances on the Domestic Substances List, mostly because the data are difficult to interpret. The NRTEE recommends that the government provide proper resources to deliver information in the simplest and most integrated way possible.

11. The NRTEE recommends that Canada investigate harmonizing its burden-of-proof criteria for substances with those in the United States.

Endnotes

1 Commissioner of the Environment and Sustainable Development, 1999 report, Chapter 3, Section 3.49, http://www.oag-bvg.gc.ca/domino/reports.nsf/html/c903ce.html

2 Commissioner, Chapter 3, Section 3.63.

3 Commissioner, Chapter 3, Section 3.60.

4 Commissioner, Chapter 3, Section 3.62.

5 Commissioner, Chapter 3, Section 3.137.

6 *Innovations and Good Practices in Single-Window Service* (Ottawa: Canadian Centre for Management Development, March 1999).

7 "Health Minister Allan Rock Outlines Amendments to *Pest Control Products Act* Before Environment Committee," *Environmental Dimensions*, February 25, 2000, p. 10.

3

Case Studies

A case-study approach was used to examine the current practices of decision making in Canada with respect to substance assessment and management.

The NRTEE's Task Force on Health, Environment and the Economy commissioned four representative case studies to illustrate different types of decision-making processes. These case studies dealt with lindane (a pesticide), sulphur in fuel, MMT (a fuel additive) and Revalor-H (a bovine growth hormone).

The case studies were developed by the Delphi Group based on interviews and other research. Great effort was made during the interview process to ensure that a balance of opinions was collected.

Each case study involved between 8 and 20 interviews. After their interviews, all interviewees received for their review and approval a copy of all quotations attributed to them in the case study.

Where appropriate, additional input obtained from this feedback process was incorporated into the final versions of the case studies. Details that could not be substantiated by additional research were either removed or attributed to the source as opinion.

The Task Force's goal in developing the case studies was to achieve a balanced and objective view of the decision-making processes surrounding particular substances. However, it should be noted that the decision to focus on these substances in no way implies agreement or disagreement with the outcome of the respective decision-making processes.

Lindane Case Study

Introduction

Background on the Substance

Lindane (>99 percent gamma isomer of hexachlorocyclohexane [HCH]) is a persistent organochlorine compound that has been in commercial use since 1938. It is used primarily as an insecticide and fumigant, and has a wide variety of applications, ranging from seed treatment for crops to control of scabies and lice in domestic and agricultural animals and in humans. In Canada, its most common use is as a treatment for canola seeds. It is a relatively low-cost pesticide, and until very recently there was no registered equivalent alternative. The use of lindane has come under scrutiny in the late 1990s for several reasons:

- Two six-year studies have found significant levels of persistent organic pollutants (POPs) in northern peoples, including high levels of the various isomers of hexachlorocyclohexane.
- Canada has signed an international protocol under the Convention on Long-range Transboundary Air Pollution (LRTAP) committing us to reassess all uses of lindane by 2002.
- The U.S. Environmental Protection Agency (EPA) has made it clear that it would be illegal to import lindane-treated canola seed into the United States, since lindane is not registered for use as a canola seed treatment in that country.
- The Canola Council of Canada and the Canadian Canola Growers Association have worked with registrants[1] to voluntarily withdraw the use of lindane for seed treatment.

Canada is currently participating in global negotiations, initiated under the United Nations Environment Programme (UNEP), to reduce and/or eliminate the use of specific persistent organic pollutants. Although lindane is not included in the proposed treaty at this time, it is being considered as a potential addition.

These factors have been critical in leading the Pest Management Regulatory Agency (PMRA) to conduct a special review of pest control products containing lindane. The following paper outlines the process and events that led up to this special review, the proposed voluntary withdrawal of lindane as a seed treatment for canola, and Canada's position on lindane in international negotiations.

Overview of the Decision-Making Process

The policy process for determining the appropriate usage and registration of lindane has been driven by two key issues, running almost in parallel to each other:

- First, the findings from several studies conducted in the Arctic indicate possible reasons to be concerned about a number of persistent contaminants. These concerns helped drive the first international negotiation process on POPs under the Convention on Long-range Transboundary Air Pollution. The negotiations resulted in lindane being restricted to six uses. Canada, as a signatory to the agreement, has committed to putting lindane under a reassessment process within two years of the protocol being ratified.
- Second, concurrent with the LRTAP negotiations wrapping up, a second pressing

economic issue put lindane under scrutiny. The U.S. EPA clarified its policy on importing seeds treated with pesticides that were not registered for use on seeds in the United States. The policy indicated that it would be illegal to import Canadian canola seed treated with lindane into the United States, since treatment with lindane was not a registered American use. This prompted immediate concern among Canadian canola growers, and discussions began among the PMRA, U.S. EPA, Canola Council of Canada and Canadian Canola Growers Association and registrants to implement a voluntary withdrawal of lindane.

Figure 1. Chronology

1938	Lindane is registered as a broad-spectrum insecticide in Canada (gamma isomer of HCH).
1970s/80s	HCH shows up in the environment, which leads to a ban on technical HCH[2] in many countries.
1972	Manufacturer voluntarily discontinues production of technical HCH in Canada and the United States.
1976	Products containing technical HCH are banned and no longer acceptable for registration in Canada.
1978	The U.S. EPA requests manufacturers of products containing technical HCH to discontinue registration of their products or to replace it with lindane.
1983	Lindane is re-evaluated in the United States, and many products are restricted.
1991	Long-range Transboundary Air Pollution Working Group on Strategies receives a scientific rationale for a POPs protocol. Northern Contaminants Program (NCP) begins research.[3]
1991	Establishment of the Arctic Monitoring and Assessment Programme (AMAP), an eight-nation program to research POP contaminants.
1994	The LRTAP Executive Body strikes an Ad Hoc Preparatory Working Group on POPs that in 1995 drafts a composite negotiating text: a document to restrict, ban or phase out uses of 15 named POPs. Thirty countries are under the chair of a Canadian public servant at the Department of Indian and Northern Affairs (DIAND), now known as Indian and Northern Affairs Canada.
1995	The Pesticide Management Regulatory Agency is created in April, combining expertise from Environment Canada, Agriculture Canada, Health Canada, and Natural Resources Canada.
1995	An Environment Canada study in the St. Lawrence valley, Quebec, shows mobile volatilization is occurring and lindane is moving away from the area of application.
1997	The chemical company Gustafson sends a letter to the EPA asking for clarification on imported treated seed.
1997	Formal LRTAP negotiations begin at the United Nations in Geneva in January.
1997	The Northern Contaminants Program issues a report, *Canadian Arctic Contaminants Assessment Report*, highlighting the persistent contaminants that have been found in the Arctic, including various POPs. The report is the culmination of six years of scientific research and more than 100 studies.
1997	An international study under the Arctic Monitoring Assessment Programme finds robust levels of beta isomers of HCH, followed by alphas and very small amounts of gamma in the blood of the Canadian Arctic population.
1997	The EPA determines that it is illegal to import lindane-treated seed, raising grave concerns among canola growers in Canada.
1998	In March, the EPA indicates that it will be illegal to import non-registered treated seed into the United States.
1998	The LRTAP POPs convention is signed in June. Lindane is a severely restricted product, with some applications allowed.
1998	Global negotiations on POPs commence under UNEP.
1998	In November, the voluntary removal of lindane is announced by the Canola Council of Canada. As of December 31, 1999, companies will stop importing and manufacturing lindane. Companies can continue to sell and farmers to use lindane until July 1, 2001.
1998	The Northern Contaminants Program begins second phase (NCP-II) to address immediate health and safety needs.
1999	The PMRA agrees to review lindane replacements on a priority basis.
1999	An alternative for lindane is approved in July.

1999	In March, the PMRA announces a special review of pest control products containing lindane. Target date for completion is December 2000.
1999	All new products, registration renewals and amended registrations that are granted in 1999 will expire and be renewed annually until December 31.
1999	Lindane is nominated in January for consideration as a candidate substance for development of a North American Regional Action Plan (NARAP) through the Commission for Environmental Co-operation (CEC).
1999	Substance selection is carried out by the Commission for Environmental Co-operation task force currently reviewing lindane.
1999	UNEP global negotiations are continuing.

Issues of Process Surrounding Lindane

A number of issues have come to light through discussions with various stakeholders on the use of lindane in Canada:

- **Lack of Transparency — The Black Box Syndrome.** Stakeholders from both inside and outside government expressed frustration at a) being unable to obtain the risk and health assessment data used by the PMRA to determine the safety of lindane, and b) not knowing the basis for decisions on product registration. This information is unavailable due to a stipulation in the *Access to Information Act* that prohibits the provision of information received in confidence to other parties.

- **Stakeholder Consultation Prior to International Negotiations.** In the first set of international negotiations there appears to have been insufficient consultation with stakeholders who would be affected by the negotiations. For example, northern Aboriginals were surprised to find out that Canada had opposed the inclusion of lindane in the LRTAP agreement on POPs, since they had seen no indication of this prior to the negotiations. The more recent UNEP negotiations have been more successful in consulting stakeholders (although lindane is not on UNEP's list).

- **Formulating Canada's International Negotiating Position.** A number of stakeholders were not clear on how Canada's international negotiating position for the LRTAP agreement had been established. There was concern that Canada's initial negotiation positions were formulated by senior-level bureaucrats with little input from Cabinet or the elected government, and therefore had little accountability. A formal process for establishing international negotiating positions was not apparent to all stakeholders.

- **Domestic Regulations Supersede International Regulations.** It is a matter of policy that Canada will not ratify any international agreements if they contradict domestic regulations, since international policy should not drive domestic measures.

- **Success with Voluntary Initiatives.** When there were major concerns about the economic consequences of using lindane as a canola seed treatment, the PMRA acted quickly and efficiently, in close consultation with the affected user groups, to find a solution. In this case, a proposal for registrants to voluntarily withdraw lindane and a quicker approvals process for alternatives to lindane have won kudos. Should the voluntary withdrawal approach work, it will result in the near elimination of lindane use in Canada.

- **Burden of Proof.** In order to instigate a special review or reassessment of a product, there must be evidence of risk from a product, even though in this case the risk assessment is quite old. The burden of proof lies on the PMRA to prove this risk is unacceptable (based on science), rather than on the registrant to prove that the product is safe.

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The Uses of Lindane

Lindane is an organochlorine insecticide and fumigant that has been used on a wide range of soil-dwelling and plant-eating insects.[4] Lindane is not produced or manufactured in Canada. It is registered for use in Canada as a broad-spectrum insecticide and acaracide. Currently, there are 44 registered products in Canada. Trade names for lindane are Premiere Plus, Vitavax RS Flowable, Vitavax RS Dynaseal, Cloak, and Foundation. Inquinosa and Rhone-Poulenc are two European-based producers of lindane.[5]

Lindane was first registered for use in Canada in 1938. Over the life of lindane, 504 lindane-containing products have been registered. Currently, 29 lindane-containing commercial products are registered. Lindane's primary use in Canada is to treat canola seed for flea beetles.[6] It is also used against ectoparasites (scabies and head lice) on animals and humans. At this time, Health Canada's on-line database lists seven different products for therapeutic use (shampoo and lotions) that contain 1 percent lindane.[7]

The Chemistry of Lindane and HCH

Lindane is a derivative of **hexachlorocyclohexane (HCH), also known as benzene hexachloride (BHC).**

Benzene hexachloride and hexachlorocyclohexane are common names for the same chemical most commonly referred to as HCH. The more formal name is 1,2,3,4,5,6-hexachlorocyclohexane. HCH has a number of isomers, of which alpha, beta, delta, gamma and epsilon are stable, and are usually the isomers found in environmental samples.

Technical HCH is a name given to one manifestation of a pesticide containing at least five isomers (approximately 60–70 percent alpha-HCH, 5–12 percent beta-HCH, 10–15 percent gamma-HCH, 6–10 percent delta-HCH and 3–4 percent epsilon-HCH).

Lindane is also a pesticide produced by using the compound HCH, and is composed of 99.5 percent gamma-HCH isomer. It is the gamma-HCH isomer, or lindane, that has the most potent insecticidal properties.

Production and Use

Global use of lindane is estimated to be 720,000 tonnes, with Canada being the sixth largest global user of lindane (gamma-HCH). Additionally, it is estimated that 55,000 tonnes of technical HCH are used worldwide.[8]

Lindane has been listed as one of the "dirty dozen pesticides" by the Pesticide Action Network North America (PANNA). It is banned from use in 28 countries, severely restricted in 18 and de-registered in one. The use of technical HCH is banned in 52 countries, restricted in 8 and de-registered in 10.[9]

> The "dirty dozen" are 18 pesticides grouped together because of their closely related chemical structures: Aldicarb (Temik); Camphechlor (Toxaphene); Chlordane; Heptachlor; Chlordimeform; DBCP; DDT; the "Drins" (Aldrin, Dieldrin, Endrin); EDB; HCH/BHC; lindane; Paraquat; Parathion; Methyl Parathion; Pentachlorophenol; and 2,4,5-T.

Large amounts of technical HCH continue to be used in India, mostly for cotton protection and malaria control.[10] The United Nations Economic Commission for Europe (UNECE) also reports that technical HCH is still widely used in Asia and the countries of the former Soviet Union. It is also suspected there are stockpiles of lindane in various African and Asian countries and in Russia.

Health and Environmental Impacts of Lindane

The major sources of lindane in the atmosphere are fugitive dust particles from wind erosion of contaminated soil, and volatilization from treated agricultural soil and from plant foliage sprayed with lindane. Lindane is removed from the

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Health and Environmental Impacts of Lindane

The major sources of lindane in the atmosphere are fugitive dust particles from wind erosion of contaminated soil, and volatilization from treated agricultural soil and from plant foliage sprayed with lindane. Lindane is removed from the atmosphere by rain and dry deposition, with levels of lindane in the atmosphere being seasonal and temperature-dependent.

Lindane can also be leached into the groundwater. It is highly soluble in water and has a tendency to remain in the water column. The estimated degradation half-lives of lindane in rivers, lakes and groundwater are 3–30 days, 30–300 days and >300 days respectively.

Lindane has the potential to bioaccumulate in organisms and to be transported over long distances. It is this persistence that makes it such an effective seed treatment but also a concern in the Arctic.

HCH is found throughout the Arctic environment. Major inputs are assumed to be from atmospheric deposition and ocean currents. It is unclear at this time whether the HCH found comes from technical HCH (still used in some countries such as India) or from lindane.[11] In addition, it is possible that gamma isomers of HCH may convert over time to the alpha isomer. Introconversion issues such as this one are confusing and still being debated.[12]

On a more positive note, measured HCH levels show a decline from 1979 to 1993. The use of one form of HCH, alpha-HCH, has declined dramatically in developing countries, contributing to a decline in overall HCH levels in the environment.[13]

Human Exposure

Humans may be exposed to the HCH compound in several ways. In some cases, lindane is used in the form of a 1 percent cream or lotion for the treatment of scabies and lice. Humans may also be accidentally exposed to HCH during the production and use of pesticide products containing the substance. Dietary exposure is the primary route of human exposure where HCH is used on food plants and animals, since it is adsorbed from the gastrointestinal tract.[14]

The finding of HCH and other POPs in the Arctic is of concern because of the potential health implications for many northern Aboriginal peoples. Arctic Aboriginal peoples tend to be more susceptible to the accumulation of contaminants in their bodies due to a traditional diet that consists of a high percentage of wildlife and/or marine mammals. Up to 91 percent of Aboriginal households in the Northwest Territories consume traditionally harvested meat and fish, and 22 percent have reported that all their meat and fish is obtained through harvest activities.[15]

Health Risks

Lindane is considered acutely and chronically toxic to humans by direct oral and inhalation routes. Environmental loadings in the Arctic vary from east to west, with North American sources more likely to end up in the eastern Arctic; however, no attempts have been made to quantify this phenomenon. It is also not really clear at this point what the health effects, especially long-term health effects, will be from higher than acceptable exposure to lindane from eating traditionally harvested foods.

The toxicity of the isomers varies. With respect to acute exposure, gamma-HCH is the most toxic, followed by alpha, delta and beta-HCH. With regard to chronic exposure (more typical in the Arctic), the beta-HCH is the most toxic followed by alpha, gamma and delta. With chronic exposure, the increased toxicity of beta isomer is probably due to its longer biological half-life in the body and its accumulation in the body with time (this could be important, since it is the alpha isomer that is most commonly found in the Arctic, although other isomers have also been detected).

Lindane is suspected of being associated with a number of health risks.

- According to the Arctic Monitoring and Assessment Programme report, "Lindane is a neurotoxin. It also adversely affects reproduction, the liver, and the immune system, and is a cancer promoter."[16]

- The U.S. EPA regulates lindane as group C, a "possible human carcinogen," while the International Agency for Research on Cancer classifies lindane as "possibly" carcinogenic to humans.[17]

- There have been mixed results with respect to the endocrine effects in aquatic organisms and mammals, with estrogenic effects found in some studies but not in others. The EPA will likely be examining lindane under the *Food Quality Protection Act* in order to determine whether it is a potential endocrine disrupter.

- Lindane exposure has been shown to have adverse effects on the immune system of fish, including immunosuppression, at sublethal concentrations of lindane (10 or 15 ppm).[18]

Economic Issues Surrounding Lindane

As lindane is an older product, one of its key benefits is its low cost while being especially effective as a seed treatment due to its persistent nature. The prime concern of canola farmers is the potential cost of effective alternatives to lindane. Farmers are also concerned that if lindane is banned without sufficient alternatives, the production of canola may become uneconomic or unfeasible. Farmers are limited as to the types of crops that they can rotate profitably, and canola is one of the more profitable crops available for farming. In addition, companies that make and sell lindane would likely experience economic consequences if the substance were to be de-registered.

Alternatives to Lindane

There are several pesticide alternatives to lindane as a seed treatment, in addition to non-pesticide possibilities. One new pesticide, Gaucho, is already registered in the United States, although it is more expensive than lindane. It was recently approved (July 1998) by the PMRA for use in Canada, although it is unknown what price it will command on the Canadian market. Other alternatives currently under review by the PMRA are Premiere 2 and Helix.[19]

According to the World Wildlife Fund, when flea beetle populations are not expected to be high, there are some non-chemical alternatives available that may provide adequate pest control. These include early planting, planting larger seeds, using no-till or direct drilling of seed, and increasing the seeding rate. Beetle damage can also be diminished by leaving a trap strip of volunteer canola near overwintering sites and cultivating the remainder of the field. The trap strip is destroyed before beetles can move into seedlings.[20] However, according to the Canola Council of Canada, non-chemical alternatives for controlling flea beetles are not feasible at this time. Options that have been looked at include parasite predators and biological means, and companies are currently looking at developing resistant varieties of canola.

Alternatives to using lindane lotion as a treatment for scabies and head lice include combing and the use of tea tree oil. In addition, the synthetic pyrethroid permethrin (5 percent cream) can be used. Permethrin is much less toxic than lindane and less easily absorbed through the skin, although it is more costly.

Account of the Policy Development, Decision-Making and Implementation Process

The following section outlines the issues and process that led up to the special review on lindane being conducted by the PMRA, and the proposed voluntary withdrawal of lindane by registrants.

Contamination in the Arctic

In the 1980s, studies on POPs in the Canadian Arctic found unexpectedly high levels unassociated with local sources. Further research in 1990 found levels of five to six POPs that exceeded Canadian health guidelines for eating flesh (primarily fish). This research launched the Northern Contaminants Program, a six-year program coordinated and led by Indian and Northern Affairs Canada (then known as the Department of Indian Affairs and Northern Development) in partnership with several federal departments (Environment Canada, Fisheries and Oceans Canada, Health Canada and the Government of the Northwest Territories), and with five Aboriginal organizations (Inuit Circumpolar Conference, Inuit Tapirisat of Canada, Dene Nation, Métis Nation — NWT, and the Council of Yukon First Nations).

In 1997, the Northern Contaminants Program issued the *Canadian Arctic Contaminants Assessment Report* — the product of more than 100 scientific studies. This study found significant levels of industrial and agricultural chemicals in the Arctic ecosystem and the people who live there. Contaminants included POPs (including HCH), heavy metals and radionuclides.[21]

In 1991, the Arctic Monitoring and Assessment Programme was established. AMAP coordinated the work of eight circumpolar countries, and ensured that the studies complemented each other and that any research gaps were covered. Canada chaired AMAP from 1993 until 1997. The pre-existing Northern Contaminants Program provided Canada's contribution to AMAP. Ultimately, two reports came out of this research: *Arctic Pollution Issues: A State of the Arctic Environment Report* was published as a simple and easy to read version in 1997; and *AMAP Assessment Report: Arctic Pollution Issues*, which contained more of the scientific research, was published in 1998. The reports were presented to the ministerial meetings of the Arctic Environmental Protection Strategy and the Arctic Council.[22]

Although it took years to publish the reports of the Northern Contaminants Program and the Arctic Monitoring and Assessment Programme, the data that formed the basis of the reports were available to the public long before publishing.[23] Recognizing the importance of community-level communication, the Northern Contaminants Program held public consultations with local communities and provided educational and communication tools related to the contaminants and to the gathering of community concerns and priorities regarding contaminants. In addition, the Northern Contaminants Program partners promoted more direct involvement by communities in the conduct of the risk management and communication processes.

Environment Canada and Indian and Northern Affairs Canada provided the data from the Northern Contaminants Program and the Arctic Monitoring and Assessment Programme to the PMRA, but the data were considered insufficient on their own to trigger a special review or re-evaluation of lindane. The studies indicated relatively low levels of lindane (i.e., gamma isomer) and slightly higher levels of beta isomer, but these were not considered to be an imminent threat to human health.[24]

International Negotiations

In 1991, Canada and Sweden persuaded the United Nations Economic Commission for Europe[25] to establish a Task Force on POPs under the Convention on Long-range Transboundary Air Pollution. In 1994, the Task Force established an Ad Hoc Preparatory Working Group on POPs and prepared a draft protocol for further negotiations.[26]

Developing Canada's Negotiating Position

In the POPs negotiations under the LRTAP, the federal government received input from stakeholders in the form of papers/letters submitted primarily to Environment Canada. Environment Canada coordinated consultations with stakeholders and provinces. It also held regular interdepartmental meetings with the core federal POPs group (which included representatives from Health Canada and Indian and Northern Affairs Canada) and with the Senior POPs Steering Committee (a federal interdepartmental committee) to discuss the development of Canada's negotiating positions and how to integrate the input received.[27]

Terry Fenge, of the Inuit Circumpolar Conference, however, suggests that the consultations were primarily conference calls involving more than 20 participants, including representatives of industry and government. The northern Aboriginal peoples did not consider this sufficient: they were uneasy participating as one interest among many. Moreover, they were acutely aware of their Aboriginal and treaty rights and the fiduciary obligations of the Crown toward them, which placed significant consultative burdens upon the federal government before it could engage in international negotiations that might affect their rights. At no stage were northern Aboriginal peoples invited to assist the federal government in developing its formal negotiating position.[28]

The northern Aboriginal peoples were also expecting Canada to include all POPs on the negotiation list, because of the recent scientific studies that had shown that the levels of POPs in northern peoples were well in excess of the "level of concern" defined by Health Canada. After the first negotiation session, in which Canada did not support making lindane part of the LRTAP protocol, the Aboriginal peoples' coalition (Inuit Circumpolar Conference, Inuit Tapirisat of Canada, Dene Nation, Métis Nation — NWT and the Council of Yukon First Nations) felt that Canada had done an about-face, and was concerned that the economic impact of including lindane was taking precedence over the public health issues. There was also concern that Canada's position was the result of agreements between federal public servants rather than Cabinet-approved instructions.[29]

The perspective of the Canadian negotiators, however, was that at the outset of the official negotiations (and despite there having been discussions on lindane during preparations for the negotiations), lindane was not among the substances that had been collectively agreed upon by countries for the initial list. It was one of a few substances still being debated — and countries had not yet agreed that lindane was a POP that required international action under the LRTAP protocol.[30]

In addition, Canada could not agree to an outright international ban on lindane, since such a move was seen as conflicting with the requirements of our own legislation (which would require lindane to be de-registered through a special review and scientific risk assessment that demonstrated substantial evidence of major health impacts occurring because of the concentrations of lindane in the environment).[31] The existing registered status of lindane would prevent Canada from ratifying the protocol.

The negotiation team considered the way forward to be a ban on technical HCH and restrictions on the use of lindane, as well as a mandatory reassessment of lindane, which would provide a more extensive scientific basis for further action on lindane as needed.[32] The rationale behind this approach was that a process to register and de-register products had already been established in Canada to protect the environment, the health of Canadians, and the economic interests of companies developing and selling pesticides. If Canada were to override this process by agreeing to a ban on lindane at the international level, it would circumvent the established national process, thereby setting a precedent for substances of future concern.

By the second LRTAP negotiating session (October 1997), a formal process was in place to ensure more thorough stakeholder communication: for example, extensive time was available to prepare interdepartmental input, briefing materials and processes were standardized, individuals were designated as subject leads on all negotiating topics, and a senior-level steering committee provided guidance. In addition, the Department of Foreign Affairs and International Trade joined Environment Canada to co-chair the process and co-head the delegation. The Department of Foreign Affairs and International Trade was seen as a natural lead for international negotiations, a neutral party with respect to Canadian chemicals management issues, and a critical player in ensuring consistency with Canada's other international obligations.[33]

Concerned about the Canadian position, the Aboriginal peoples' coalition used the Inuit Circumpolar Conference's "consultative status" to the UN Economic and Social Council to send an observer to the session. They believed that Canada was taking a more conservative position than virtually any other nation, which seemed at odds with Canada's earlier successful attempts to persuade LRTAP countries to negotiate a POPs protocol.[34] Later that year, the Inuit Circumpolar Conference formally asked the PMRA for copies of the risk assessment and supporting data forming the basis of Canada's regime for lindane. The PMRA, however, was unable to provide this information, due to the confidentiality provisions under the *Access to Information Act*.

In the October 1997 negotiations, the Aboriginal peoples tabled a paper that, if adopted, would partially ground the LRTAP POPs protocol in Arctic, Aboriginal and public health concerns. In subsequent meetings, some of the preambular language was accepted. In addition, Canada now accepted that lindane could be included in the protocol as a restricted substance, but insisted, along with other countries such as the United Kingdom, that all current uses of the pesticide be allowed to continue.[35]

The LRTAP negotiations wrapped up in the summer of 1998, and the resulting convention covered 16 substances, with a provision for adding substances. The agreement was signed in 1998 by 34 countries. Under the agreement, technical HCH is restricted to use as an intermediate in chemical manufacturing and lindane is restricted to six uses, three of which are registered in Canada. These are:

1. seed treatment;
2. soil applications directly followed by incorporation into the topsoil surface layer;
3. public health and veterinary topical insecticide.

The condition stated in the protocol is that "all restricted uses of Lindane shall be reassessed under the Protocol no later than two years after entry into force." The protocol does not enter into force until 16 countries have ratified the protocol. This is estimated to take between two and two and a half years, so entry into force would occur in 2000 and the reassessment two years later, that is, in 2002.[36]

Although this required reassessment of lindane did not drive the special review process, it has been a critical factor in making the special review of lindane a high priority in the PMRA.[37]

Global Negotiations — UNEP

In February 1997, the Governing Council of the United Nations Environment Programme decided to initiate immediate international action "to protect human health and the environment through measures which will reduce and/or eliminate . . . the emission and discharges" of 12 listed POPs.[38] Just as the LRTAP negotiations were wrapping up, the UN began global negotiations on POPs (July 1998). These were driven by a recommendation from the International Forum on Chemical Safety.

UNEP Governing Council Decision Document GC 19/13C outlines the negotiating mandate for the POPs Intergovernmental Negotiating Committee. Negotiations are still ongoing. Lindane is not included in the initial list of substances, as outlined in the Governing Council Decision Document, although provisions are being worked on for adding other substances in the future.[39] In contrast, in the earlier negotiations that led to the 1998 protocol on POPs under the LRTAP, negotiators determined the substances included in the original agreement.[40]

There is no direct connection between the LRTAP and UNEP POPs negotiations. However, some stakeholders have commented that the UNEP process is an improvement over its LRTAP predecessor. These improvements include much more comprehensive consultation and discussion with key stakeholders, such as the Inuit Circumpolar Conference, and the inclusion of representatives of Aboriginal peoples, industry and environmental groups directly on the Canadian delegation.[41] One farmer expressed strong support for the "fabulous job" that Environment Canada has done in conducting a "proper consultation" on the issues of POPs international negotiations.[42] In addition, having gone through the LRTAP POPs process, the negotiators have some notification of the positions that some stakeholders may take in the UNEP POPs negotiations.[43] Despite these improvements, there is still frustration that Canada is only slowly defining its position on key issues.[44]

EPA Ruling on Imported Treated Canola Seed

In September 1997, the chemical company Gustafson asked the EPA to clarify its position on treated seed being imported into the United States. The EPA determined that it would be illegal to import seeds treated with pesticides that were not registered for that specific purpose into the United States. Lindane-treated canola seed fell under this policy (even though lindane is registered for other seed treatment uses in the United States).[45] Then, in the spring of 1998, a shipment to the United States of canola seed treated with lindane was stopped. Canadian canola growers, the Canola Council of Canada, as well as canola farmers in North Dakota were alarmed at a potential scenario in which the United States could stop any treated seed used for planting being moved south of the border. In addition, if lindane residues were detected in seed for crushing of meal or oil, the United States could stop the movement of these products.

For Canadian farmers this was a serious issue. One canola farmer explained that any crop may have 50 to 100 pests, and each one could reduce the yield, depending on the severity of the infestation, by up to 100 percent. Therefore, farmers need a selection of tools to deal with different pests, and to reduce the risk of resistance developing. The loss of lindane could be critical to the control of pests, and could determine whether growing canola was viable or not.[46]

In response, the Canola Council of Canada looked at what was happening worldwide with lindane and determined that alternative products were needed. The Council met with the registrant companies, growers and the PMRA, and the growers proposed to have registrants voluntarily withdraw canola from the registration label as long as alternative seed treatments were available for flea beetle control.

The PMRA played an important role in the proposed voluntary withdrawal. Since growers needed alternatives quickly, the PMRA[47] worked in close collaboration with stakeholders and set up the opportunity for priority review of alternative products by sending the message out to registrants. Three potential alternatives were received, one of which was not reviewable (i.e., did not have a complete package according to standards), which resulted in two potential alternatives for review.

The farming community was consulted through their associations about the proposed withdrawal of lindane. A prime concern initially was the potential loss of the U.S. market for their product. However, there was also concern about losing a very effective tool for pest control on canola and other, minor crops, with the possibility of no alternatives being available.

While the approval time for new active ingredients is usually 18 months, the approval process for lindane alternatives was speeded up. To find new seed treatments that are viable in both countries, the PMRA worked with the EPA, the Canola Council of Canada and its U.S. counterparts to jointly evaluate new compounds. They also made a commitment to complete the joint review and register approved alternatives by 2000.[48] One pesticide alternative, Gaucho, was registered in July 1999. It is considered safer from an environmental and health perspective and will be available for the 2000 growing season. However, its cost is unknown, which is a concern to growers.[49]

The voluntary withdrawal comes into effect on December 31, 1999, at which point chemical companies will no longer import or manufacture lindane. They can, however, continue to sell lindane to farmers, who can use the product until July 1, 2001. The U.S. Food and Drug Administration has agreed not to take any regulatory or trade action against canola seeds coming across the U.S. border as a commodity, due to the voluntary action being taken by Canadian companies and growers.[50]

Endocrine Disrupters

Although several Canadians thought that the *Food Quality Protection Act* was the trigger for the U.S. import action on canola seed, Anne Lindsay, Director of the Field and External Affairs Division of the Pesticides Office of the U.S. EPA, stated unequivocally that it was not. The new *Food Quality Protection Act* establishes an endocrine disrupter screening and testing program over a four-year period and will then report back to Congress. It will cover all industrial chemicals and pesticides (over 90,000), of which lindane may be one since most POPs are included on the list.[51]

Special Review by the PMRA

By signing the LRTAP protocol, Canada made a commitment to restrict the uses of lindane and to conduct a reassessment (special review) of all remaining uses. On March 15, 1999, the PMRA notified registrants and other interested parties that pest control products containing the active ingredient lindane would be subject to this special review[52] under Section 19 of the Pest Control Products Regulations. In the notice, it stated that the decision to review was influenced by the ongoing national and international scrutiny that lindane is receiving as a result of its persistence, potential for long-range transport and widespread occurrence in the environment.[53]

The first step of this review is to obtain new data from the registrants on the chemistry of ingredients. The PMRA has also written to other government departments and provinces for any information they may have, in addition to working closely with the United States on this issue, since the EPA is also reassessing lindane. The PMRA is also cognizant of the studies in various European countries. After the information is gathered, lindane will undergo a risk assessment review to determine whether the risks (e.g., dietary exposure, worker exposure) are still acceptable based on newer standards. Based on the risk assessment, the registration permits may be changed to allow for new, fewer, different, or no permitted applications for lindane. Personnel at the PMRA state that they are trying to be as focused and as efficient as possible in coming to a decision, while following the *Pest Control Products Act*.[54]

Lindane Endnotes

1 Registrants are those companies that sell, manufacture, and/or reformulate products that fall under the *Pest Control Products Act*.

2 "Technical HCH" is a pesticide with mixed isomers of HCH. Lindane, on the other hand, is composed mostly of the gamma-HCH isomer.

3 Fenge, Terry. "POPs in the Arctic: Turning Science into Policy." *Northern Perspectives*. Volume 25, Number 2, Winter 1998.

4 Extension Toxicology Network. http://pmep.cce.cornell.edu/profiles/extoxnet/haloxyfop-methylparathion/Lindane-ext.htm.

5 Meakin, Stephanie. Technical Advisor for Canadian Arctic Indigenous Peoples against POPs. Research notes.

6 Buth, Joanne. Vice-President, Canola Council of Canada. Personal interview. August 23, 1999.

7 Health Canada. http://www.hc-sc.gc.ca/hpb/drugs-dpd.

8 Indian and Northern Affairs Canada. *Canadian Arctic Contaminants Assessment Report*. 1997.

9 Pesticide Action Network North America. *Demise of the Dirty Dozen*. 1998. http://www.ig.capc.org/panna/campaigns.DD.html.

10 Biegel, Wolfgang (ed.). *Lindane: Answers to Important Questions*. Centre International d'Études du Lindane (CIEL). Brussels. 3rd Edition. 1995.

11 Indian and Northern Affairs Canada. *Canadian Arctic Contaminants Assessment Report*.

12 Nomination Dossier for Lindane. Submission by the United States to the Working Group for the Sound Management of Chemicals (SMOC) for consideration as a candidate for development of a North American Regional Action Plan. January 15, 1999.

13 Furgal, Chris M., and Keith, Robbie. "Contaminants Assessment Report: Overview and Summary." *Northern Perspectives*. Volume 25, Number 2, Winter 1998.

14 Meakin, Stephanie. Research notes.

15 Furgal, Chris M., and Keith, Robbie. *Northern Perspectives*.

16 Arctic Monitoring and Assessment Programme. *AMAP Assessment Report: Arctic Pollution Issues*. Oslo. 1998.

17 Nomination Dossier for Lindane.

18 Dunier et al. "Effect of lindane exposure on rainbow trout immunity." *Ecotoxicol Environ Safety*. Number 30, 1995: 259–68.

19 Buth, Joanne. Personal interview.

20 World Wildlife Fund Canada. Personal communication. October 6, 1999.

21 Furgal, Chris M., and Keith, Robbie. *Northern Perspectives*.

22 Stone, David. Director of Northern Science Contaminants Research, Indian and Northern Affairs Canada. Personal interview. August 21, 1999.

23 Fenge, Terry. Director of Research, Inuit Circumpolar Conference. Personal interview. July 27, 1999.

24 Gilman, Andy. Director, Bureau of Sustainable Development, Health Protection Branch, Health Canada. Personal interview. August 3, 1999. (All statements made by Dr. Gilman reflect his personal understanding of the lindane issue at that time.)

25 The UNECE's membership includes western and southern European countries, Canada, the United States, Russia and other eastern European states. It has assumed a key role in facilitating a number of environmental agreements.

26 Bankes, Nigel. "Steps towards the International Regulation of POPs." *Northern Perspectives.* Volume 25, Number 2, Winter 1998.

27 Fortin, Suzanne. Senior Policy Advisor, Environmental Affairs Branch, Industry Canada. Personal interview. August 25, 1999.

28 Fenge, Terry. *Northern Perspectives.*

29 Ibid.

30 Fortin, Suzanne. Personal interview.

31 Gilman, Andy. Personal interview.

32 Fortin, Suzanne. Personal interview.

33 Ibid.

34 Fenge, Terry. *Northern Perspectives.*

35 Ibid.

36 Meakin, Stephanie. Research notes.

37 Sexsmith, Wendy. Director of Alternative Strategies and Regulatory Affairs Division, PMRA. Personal interview. August 11, 1999.

38 Bankes, Nigel. *Northern Perspectives.*

39 Fortin, Suzanne. Personal interview.

40 Stone, David. Personal interview.

41 Fenge, Terry. Personal interview.

42 Wilson, Jeff. Farmer. Personal interview. August 20, 1999.

43 Fortin, Suzanne. Personal interview.

44 Fenge, Terry. Personal interview.

45 Lindsay, Anne. Director, Field and External Affairs Division, Pesticides Office, EPA. Personal interview. August 24, 1999.

46 McPhee, Gordon. Canola producer. Personal interview. August 20, 1999.

47 Buth, Joanne. Personal interview.

48 Lindsay, Anne. Personal interview.

49 Buth, Joanne. Personal interview.

50 Buth, Joanne. Personal interview, October 8, 1999.

51 Lindsay, Anne. Personal interview.

52 In Canada, two types of reviews are possible: a complete re-evaluation of the product or a special review, which can be conducted on a specific subset of issues of concern (e.g., just environmental). The process is only triggered by new data indicating a health or environmental impact. The PMRA assesses the new information and makes a judgment as to whether the weight of evidence demonstrates an unacceptable risk.

53 Pest Management Regulatory Agency. *Special Review Announcement.* SRA99-01. Special Review of Pest Control Products Containing Lindane. March 15, 1999.

54 Sexsmith, Wendy. Personal interview.

Reducing Sulphur in Gasoline and Diesel Fuel Case Study

B

Introduction

Background on the Substance

Sulphur is found in Canadian gasoline and diesel fuels in varying concentrations across the country. High sulphur levels in fuel increase the emissions of a host of pollutants, such as sulphur dioxide (SO_2), carbon monoxide (CO), nitrogen oxides (NOx), volatile organic compounds (VOCs) and fine particulate matter (PM2.5), some of which also contribute to the formation of secondary pollutants such as ground-level ozone. These emissions are linked to adverse health effects in Canadians, particularly those living in large urban centres. Efforts to reduce emissions from individual vehicles through emissions control technologies are expected to continue. However, based on the increasing number of vehicles in use and increased vehicle usage patterns, the overall contribution of the transportation sector to air pollution is expected to rise over time.[1,2]

The reduction of air pollutants is clearly a priority health and environmental challenge for Canada. However, the need for control measures is also being spurred by sulphur's adverse effect on the operation of emission control technologies in existing vehicles and, more significantly, on the emerging low-emission vehicles (LEVs). The introduction of LEVs is an important tool for future efforts to reduce pollution, including carbon dioxide (CO_2) emissions.

Regulating the sulphur content of fuel has economic and social benefits for society, as well as cost and competitiveness implications for the refining industry. Policy makers within Environment Canada have considered the economic impacts of such regulation on Canadian refiners and independent marketers in relation to the health, environmental and economic benefits for society of reduced pollution. The outcome of their efforts was a decision to regulate sulphur to an average of 30 parts per million (ppm) with a never-to-be-exceeded limit of 80 ppm by the year 2005. The decision to regulate sulphur in gasoline in this way was motivated primarily by the significant potential health benefits of reducing sulphur-related air emissions. As stated in the regulatory impact analysis statement of the Sulphur in Gasoline Regulations, "the *Sulphur in Gasoline Regulations* will protect the health of Canadians and the environment."[3]

Fuel formulation has become an important component of cleaner air initiatives for a number of reasons:

- Air pollutants compromise the health of Canadians, and motor vehicles are a significant contributor to poor air quality.
- The sulphur in gasoline and diesel fuel contributes to overall air pollution, which negatively affects the health of Canadians and their environment.
- There are significant costs associated with the health impacts arising from air pollution.
- The sulphur content of Canadian fuel is one of the highest in the world (Ontario's average is the highest in Canada), and many other OECD countries are taking steps to control sulphur levels in gasoline and diesel fuels.
- High sulphur levels in gasoline adversely affect the performance of existing vehicle emissions

control equipment, as well as the performance of emerging technologies to be used in the next generation of low-emission vehicles.

Overview of the Decision-Making Process

Establishing limits for sulphur in gasoline and diesel fuel is one aspect of a larger program for clean air that has involved many federal, provincial and municipal actions and a broad consultative effort. The first documented evidence of a concerted effort to address sulphur in fuel appears in a report completed by Transport Canada and Environment Canada entitled *A Plan to Identify and Assess Emission Reduction Opportunities from Transportation, Industrial Engines and Motor Fuels*, released in May 1989.

Since that time, two significant formal processes have been convened to consider the control of sulphur levels in gasoline. The first major effort was undertaken by the Canadian Council of Ministers of the Environment (CCME), referred to in this report as the "CCME Process." The second effort was led by Environment Canada at the direction of the CCME, and will be referred to as the "Sulphur Panel Process." Environment Canada used the Sulphur Panel Process results, summarized in the *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel* [4] to establish the Sulphur in Gasoline Regulations,[5] which limit sulphur in gasoline to an average of 30 ppm with a never-to-be-exceeded limit of 80 ppm to be implemented by 2005. The Regulations also include an interim requirement of a 150 ppm average from mid-2002 to December 2004.

Chronology

The policy process to address sulphur levels in Canadian gasoline and diesel is well documented. The major milestones in Figure 1 have been highlighted in boldface for ease of reference. More detailed descriptions of these milestones are provided in the following text. The remaining milestones listed in Figure 1 are not directly tied to efforts to regulate sulphur and are provided for context.

Figure 1. Chronology

1988	The federal government introduces new light- and heavy-duty vehicle emissions standards under the *Motor Vehicle Safety Act*, which take effect September 1, 1987, and December 1, 1988, respectively. At the time, these standards are considered some of the tightest in the world.
1989	In May, Transport Canada and Environment Canada release A Plan to Identify and Assess Emission Reduction Opportunities from Transportation, Industrial Engines and Motor Fuels.
1994	The U.S. Environmental Protection Agency (EPA) regulates on-road diesel sulphur levels to 500 ppm. In Canada, refiners sign a Memorandum of Understanding to start voluntarily introducing diesel fuel with sulphur levels of no more than 500 ppm.
1995	The U.S. EPA releases the Federal Reformulated Gasoline Program targeting U.S. regions that are out of compliance with National Ambient Air Quality Standards.
1995	**The Canadian Council of Ministers of the Environment endorses the *Final Report of the Task Force on Cleaner Vehicles and Fuels* (CCME Process).**
1996	**Environment Canada, acting on recommendations of the CCME, forms expert panels and a steering committee that includes representatives of key partners: provinces, Health Canada, the Canadian Petroleum Products Institute and others (Sulphur Panel Process).**
1997	**Environment Canada promulgates the Diesel Fuel Regulations in February and the Benzene in Gasoline Regulations in November as per the CCME direction.**
1997	**The Government Working Group convenes to consider the expert panel reports, to formulate options and recommendations, and to conduct the broader stakeholder consultation process (Sulphur Panel Process).**
1997	The CCME's Vehicle/Fuels Compatibility Task Group releases its report in July.
1998	**The final report and recommendations of the Government Working Group are released in July.**

1998	**The Sulphur in Gasoline Regulations are published in the *Canada Gazette*, Part I, and submissions are received from a broad range of stakeholders in October.**
1999	**The Sulphur in Gasoline Regulations are published in the *Canada Gazette*, Part II, on June 23.**
1999	The U.S. EPA announces its intention to regulate lower sulphur levels in conjunction with Tier II vehicle emission standards, effective 2004.
1999	The U.S. EPA introduces the Voluntary National Low-Emission Vehicle (NLEV) program to the northeastern states; introduction to the remainder of the United States is scheduled for 2000.
2004	Tier II vehicle standards will begin implementation in the United States; complete implementation expected by 2008.

Issues of Process Surrounding the Sulphur in Gasoline Regulations

During the preparation of the case study, several key developments emerged that were important in shaping the policy debate on sulphur in gasoline and diesel:

- **National versus international policy development and trade** surfaced frequently as a theme, due to the refining industry's calls for Canada to delay the Sulphur in Gasoline Regulations in order to harmonize with U.S. policy on fuel formulation.

- **Shared decision making** was a key component of the Sulphur Panel Process (e.g., in the selection of panel participants).

- **New processes** were tried in the Sulphur Panel Process. For example, the process included consensus-based, third-party expert panels as well as a federal–provincial working group to establish a national level for sulphur in gasoline. The process was open to stakeholder and public input (e.g., the Government Working Group's report was circulated to over 200 stakeholders for input, and public forums were held to discuss the findings).

- **New tools and methods**, including state-of-the-art modelling, valuation and analytical techniques, were used by the independent expert panels to develop estimates of the potential health benefits and economic costs. These estimates were used as the basis for the cost–benefit analysis. The tools used to estimate the cost and competitiveness impacts on the refining industry were not challenged. However, the tools used to estimate the health and economic benefits were a source of contention for a few stakeholders (see discussion on the Health and Environmental Impact Assessment Panel, section "Expert Panel and Government Working Group for Sulphur in Gasoline and Diesel"). Each result was achieved using the same consensus-based expert panel process.

- **Vehicle/fuel interaction** surfaced as a key driver in the consideration of sulphur fuel regulations. The possibility of further reducing emissions using new vehicle emission control technology is reaching a technical barrier, and further progress will likely be difficult without changes in fuel formulation (e.g., lower sulphur levels). As well, the negative impact of sulphur on existing and emerging technologies was a frequent consideration. A call for a systems approach that considers the interplay between vehicle and fuel was raised within the process and by interview participants.

- **The economic impacts** on industry and society of reducing sulphur in gasoline were assessed in billions of dollars for the refining industry, and in cents per litre for consumers. The competitiveness implications were outlined in terms of potential refinery closures and corresponding job losses. Potential economic benefits from industry's environmental spending were estimated in person years. Potential health benefits were estimated numerically in terms of avoided health outcomes, and then these avoided health outcomes were translated into monetary terms.

control equipment, as well as the performance of emerging technologies to be used in the next generation of low-emission vehicles.

Overview of the Decision-Making Process

Establishing limits for sulphur in gasoline and diesel fuel is one aspect of a larger program for clean air that has involved many federal, provincial and municipal actions and a broad consultative effort. The first documented evidence of a concerted effort to address sulphur in fuel appears in a report completed by Transport Canada and Environment Canada entitled *A Plan to Identify and Assess Emission Reduction Opportunities from Transportation, Industrial Engines and Motor Fuels*, released in May 1989.

Since that time, two significant formal processes have been convened to consider the control of sulphur levels in gasoline. The first major effort was undertaken by the Canadian Council of Ministers of the Environment (CCME), referred to in this report as the "CCME Process." The second effort was led by Environment Canada at the direction of the CCME, and will be referred to as the "Sulphur Panel Process." Environment Canada used the Sulphur Panel Process results, summarized in the *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel*[4] to establish the Sulphur in Gasoline Regulations,[5] which limit sulphur in gasoline to an average of 30 ppm with a never-to-be-exceeded limit of 80 ppm to be implemented by 2005. The Regulations also include an interim requirement of a 150 ppm average from mid-2002 to December 2004.

Chronology

The policy process to address sulphur levels in Canadian gasoline and diesel is well documented. The major milestones in Figure 1 have been highlighted in boldface for ease of reference. More detailed descriptions of these milestones are provided in the following text. The remaining milestones listed in Figure 1 are not directly tied to efforts to regulate sulphur and are provided for context.

Figure 1. Chronology

1988	The federal government introduces new light- and heavy-duty vehicle emissions standards under the *Motor Vehicle Safety Act*, which take effect September 1, 1987, and December 1, 1988, respectively. At the time, these standards are considered some of the tightest in the world.
1989	In May, Transport Canada and Environment Canada release A Plan to Identify and Assess Emission Reduction Opportunities from Transportation, Industrial Engines and Motor Fuels.
1994	The U.S. Environmental Protection Agency (EPA) regulates on-road diesel sulphur levels to 500 ppm. In Canada, refiners sign a Memorandum of Understanding to start voluntarily introducing diesel fuel with sulphur levels of no more than 500 ppm.
1995	The U.S. EPA releases the Federal Reformulated Gasoline Program targeting U.S. regions that are out of compliance with National Ambient Air Quality Standards.
1995	**The Canadian Council of Ministers of the Environment endorses the *Final Report of the Task Force on Cleaner Vehicles and Fuels* (CCME Process).**
1996	**Environment Canada, acting on recommendations of the CCME, forms expert panels and a steering committee that includes representatives of key partners: provinces, Health Canada, the Canadian Petroleum Products Institute and others (Sulphur Panel Process).**
1997	**Environment Canada promulgates the Diesel Fuel Regulations in February and the Benzene in Gasoline Regulations in November as per the CCME direction.**
1997	**The Government Working Group convenes to consider the expert panel reports, to formulate options and recommendations, and to conduct the broader stakeholder consultation process (Sulphur Panel Process).**
1997	The CCME's Vehicle/Fuels Compatibility Task Group releases its report in July.
1998	**The final report and recommendations of the Government Working Group are released in July.**

1998	**The Sulphur in Gasoline Regulations are published in the *Canada Gazette*, Part I, and submissions are received from a broad range of stakeholders in October.**
1999	**The Sulphur in Gasoline Regulations are published in the *Canada Gazette*, Part II, on June 23.**
1999	The U.S. EPA announces its intention to regulate lower sulphur levels in conjunction with Tier II vehicle emission standards, effective 2004.
1999	The U.S. EPA introduces the Voluntary National Low-Emission Vehicle (NLEV) program to the northeastern states; introduction to the remainder of the United States is scheduled for 2000.
2004	Tier II vehicle standards will begin implementation in the United States; complete implementation expected by 2008.

Issues of Process Surrounding the Sulphur in Gasoline Regulations

During the preparation of the case study, several key developments emerged that were important in shaping the policy debate on sulphur in gasoline and diesel:

- **National versus international policy development and trade** surfaced frequently as a theme, due to the refining industry's calls for Canada to delay the Sulphur in Gasoline Regulations in order to harmonize with U.S. policy on fuel formulation.
- **Shared decision making** was a key component of the Sulphur Panel Process (e.g., in the selection of panel participants).
- **New processes** were tried in the Sulphur Panel Process. For example, the process included consensus-based, third-party expert panels as well as a federal–provincial working group to establish a national level for sulphur in gasoline. The process was open to stakeholder and public input (e.g., the Government Working Group's report was circulated to over 200 stakeholders for input, and public forums were held to discuss the findings).
- **New tools and methods**, including state-of-the-art modelling, valuation and analytical techniques, were used by the independent expert panels to develop estimates of the potential health benefits and economic costs. These estimates were used as the basis for the cost–benefit analysis. The tools used to estimate the cost and competitiveness impacts on the refining industry were not challenged. However, the tools used to estimate the health and economic benefits were a source of contention for a few stakeholders (see discussion on the Health and Environmental Impact Assessment Panel, section "Expert Panel and Government Working Group for Sulphur in Gasoline and Diesel"). Each result was achieved using the same consensus-based expert panel process.
- **Vehicle/fuel interaction** surfaced as a key driver in the consideration of sulphur fuel regulations. The possibility of further reducing emissions using new vehicle emission control technology is reaching a technical barrier, and further progress will likely be difficult without changes in fuel formulation (e.g., lower sulphur levels). As well, the negative impact of sulphur on existing and emerging technologies was a frequent consideration. A call for a systems approach that considers the interplay between vehicle and fuel was raised within the process and by interview participants.
- **The economic impacts** on industry and society of reducing sulphur in gasoline were assessed in billions of dollars for the refining industry, and in cents per litre for consumers. The competitiveness implications were outlined in terms of potential refinery closures and corresponding job losses. Potential economic benefits from industry's environmental spending were estimated in person years. Potential health benefits were estimated numerically in terms of avoided health outcomes, and then these avoided health outcomes were translated into monetary terms.

Sulphur's Role in Air Quality and Human and Environmental Health

Concerns related to the health effects of air pollution, especially in urban settings, have been a primary driving force in both the CCME Process and Sulphur Panel Process. As indicated earlier, sulphur in gasoline and diesel fuel contributes to emissions of various pollutants, some of which play a role in the formation of secondary pollutants such as ground-level ozone. The existence of all of these pollutants contributes to the prevalence and severity of respiratory and cardiac ailments in the Canadian population. For example, episodes of bronchitis and asthma in children and the prevalence of chronic bronchitis have been linked to poor air quality. Children and individuals with pre-existing medical conditions are at greatest risk.

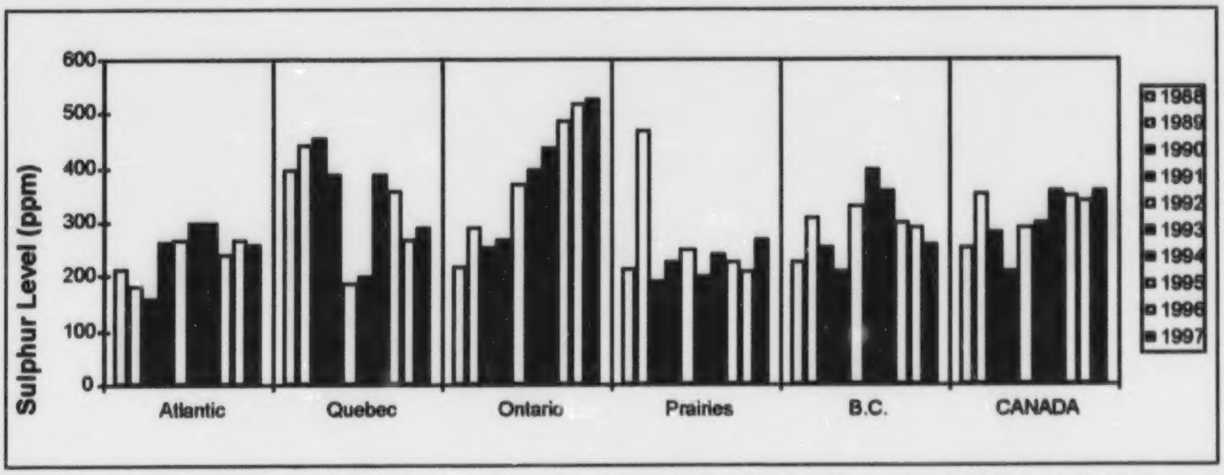
Although there is evidence that air pollution causes negative health effects, debate exists over which pollutants (or combination of pollutants) are most to blame for these effects and from what sources the emissions are coming. This debate is an important dimension of the sulphur in gasoline case study.

Some of the pollutants stemming from sulphur in fuel also contribute to environmental and economic challenges, such as lake acidification from acid rain. The CCME Task Force on Cleaner Vehicles and Fuels also defined carbon dioxide as an air pollutant for the purpose of broadening the scope of the CCME Process to include climate change as an environmental issue. Existing levels of sulphur in gasoline may prevent the introduction of new LEVs, which are considered by the CCME to be an integral component of future efforts to curb greenhouse gases.

Sulphur Content in Canadian Fuels

Canadian gasoline contains, on average, 350 ppm of sulphur, which is one of the highest levels in industrialized countries. The sulphur content of Canadian fuels reflects the concentration of sulphur in the crude oil and the refining process used in the production of the fuel. The source and type of crude oil vary between provinces and refineries. Additionally, the technology of refining processes can vary substantially. These factors contribute to variations in fuel sulphur concentrations, which range from below 30 ppm to above 500 ppm in Canada. Current Canadian standards allow up to 1000 ppm sulphur in gasoline. Regional variations in gasoline sulphur content are illustrated in Figure 2.

Figure 2. Regional Sulphur Levels in Gasoline



Source: *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel*, July 1998.

Sulphur and Vehicle Emissions

Sulphur is removed, to varying degrees, during the refining of crude oil into automotive fuel and other products. The remaining sulphur in fuel is emitted from vehicle engines largely in the form of gaseous sulphur dioxide and particulate sulphate, and to a lesser degree in combination with organic compounds. The quantity of vehicle sulphur emissions is governed by several factors:

1. the sulphur content of the fuel;
2. the emission control technology employed by the vehicle;
3. the operating efficiency of the emission control technology.

Fuel composition and vehicle technology (engine and emission control design) are both important factors that affect vehicle emissions. As vehicle emission standards have become increasingly stringent, greater emphasis has been placed on the role of both technology and fuel, to the extent that a total systems approach is now considered key to meeting future vehicle emission standards.

Account of the Development, Decision-Making Process and Implementation of the Sulphur in Gasoline Regulations

Several key factors were debated throughout the process that are important to understanding the key decision-making processes.

Harmonization

The Refiners

The position of the refiners throughout this policy effort has been that the logical course of action for their industry is to remain in step with U.S. efforts to regulate fuel sulphur content. This is similar to the government strategy (lock-step policy) used for the automotive sector in implementing emission control technology introduced in the United States. The rationale for harmonization suggests that Canadian policy created in advance of a U.S. decision to regulate sulphur to a set limit threatens the economic viability of Canadian refineries.

U.S. EPA Process

The U.S. Environmental Protection Agency (EPA) recently announced its proposal to establish a national 30/80 ppm sulphur in fuel regulation starting in 2004. This would appear to reduce some of the risks to Canadian industry.

The Government's Position

The government response to the question of whether to wait for the EPA's regulatory decision was that action to reduce sulphur levels in gasoline in Canada was warranted regardless of any action taken in the United States.

Health Impacts, Valuation and Uncertainties

The debate over the translation of sulphur reduction scenarios into projected impacts on public health, the subsequent monetary valuation of the avoided health impacts, and the uncertainties associated with the methods used was the most contentious element of the expert panel deliberations. As similar policy processes arise in the future, the selection of the methodology and analytical tools to be used will likely be the first point of discussion. As with any scientific debate, the methodologies, and by extrapolation the results, will change only when scientific research and debate suggest a better means of obtaining the results, and a consensus on a better way of performing this type of complex analysis emerges.

Economic Impacts

The economic impacts of regulating sulphur content in fuels include both economic and social benefits for society derived from improved public health, and the cost and competitiveness implications for the refining industry. There are additional potential cost implications for the automotive sector, which were also incorporated into the debate.

Cost and Competitiveness in Canadian Refineries

The potential costs to the refinery sector were studied by the Cost and Competitiveness Panel of the Sulphur Panel Process. The impacts on competitiveness in the Canadian fuel market are derived, in part, from:

1. the economic impacts of retooling refineries;
2. the increased operational costs associated with the additional energy and resources required to extract sulphur;
3. the economic risk associated with the possible selection of an inappropriate technology (the implementation of sulphur regulations in advance of the United States may require Canadian refiners to adopt outdated, higher cost technologies or processes).

Efforts to reduce sulphur levels in gasoline and diesel may represent a financial risk to some refineries in Canada.

Implications for Vehicle Manufacturers

The economic impacts for vehicle manufacturers are linked to the potential repair costs of emission control equipment that may be fouled by current sulphur levels in gasoline and diesel fuel. The manufacturers maintain that existing sulphur levels in fuel are already causing emission control equipment on existing Tier 0 and Tier I vehicles to operate below performance specifications. They also claim that newer technologies employed on Tier II vehicles (low-emission and ultra-low-emission vehicles) may be even more adversely affected. If the existing levels of sulphur in fuel make vehicles non-compliant with federal regulations governing emissions, the resulting costs would have to be borne by the manufacturers.

Social and Economic Benefits

The Health and Environmental Impact Assessment Panel attempted to estimate the benefits (social and economic) derived from avoiding health effects, such as reduced medical costs or lower rates of premature death. As quantified by the Air Quality Valuation Model (AQVM), these benefits outweighed the costs to industry by two to one. Some stakeholders expressed great concern about using the data obtained from the AQVM as a basis for the formulation of public policy.

Another economic benefit of reducing sulphur levels in fuel is linked to the capital costs associated with retooling refineries, in the form of jobs in the construction industry and in the equipment and services sectors. These jobs are estimated to offset some of the short-term societal economic impacts of adjusting to the sulphur regulations. Since the distribution of potential jobs will vary considerably across the country, economic hardships may be experienced in communities where refineries close.

Regulatory Changes to Vehicle Standards

The federal government, acting under the *Motor Vehicle Safety Act*, revised the emission standards for light- and heavy-duty vehicles in 1988. This effort, following similar actions in the United States, resulted in the introduction of new emission control technologies to meet the more stringent standards. A lock-step Canadian technology policy ensured that U.S. changes in emission control equipment were implemented simultaneously in Canada. This policy was effective, given that Canada's automotive market represented approximately 8 percent of the North American market.

Transport Canada and Environment Canada's Plan

The joint effort of Transport Canada and Environment Canada to manage the priority issue of vehicle emissions culminated in the publication *A Plan to Identify and Assess Emission Reduction Opportunities from Transportation, Industrial Engines and Motor Fuels.*[6] The plan, which was published in May 1989, was followed by extensive public consultation sessions that began in September 1989. Several hundred participants, representing a cross-section of industry, non-governmental organizations, federal and provincial departments, and the public, were consulted on the plan.

The joint plan included a multi-year research effort to identify the availability and impacts of technology and management strategies, including fuel composition, on vehicle emissions. The plan stated that proposals for control regulations would be defined and implemented by the mid-1990s. However, these regulations were never developed, since the plan was by-passed with the introduction of the Task Force on Cleaner Vehicles and Fuels under the CCME.

The Task Force on Cleaner Vehicles and Fuels (CCME Process)

The CCME established the Task Force on Cleaner Vehicles and Fuels on November 8, 1994, giving it a mandate to develop options and recommendations on a national approach to new vehicle emission and efficiency standards and fuel formulations for Canada. The CCME struck the Task Force to address, in part, the increasing problem of air pollution from vehicle usage, especially in densely populated urban centres.

The Task Force's Mandate

To develop options and recommendations to the Council of Ministers on a national approach to new vehicle emissions and efficiency standards and fuel formulations for Canada, recognizing regional/urban realities.

The Task Force was co-chaired by Environment Canada and British Columbia's Ministry of Environment, Lands and Parks and was composed primarily of the deputy ministers of the provincial environment departments. Transport Canada was the only federal department participating fully on the Task Force; Industry Canada and Natural Resources Canada were invited as ex officio members.

The Task Force struck two additional bodies, the Working Group and the Advisory Group. Figure 3 provides an organizational chart of the CCME Process. The Working Group was responsible for summarizing and consolidating the technical reports and acting as liaison between the Advisory Group and the Task Force. This body was composed of federal and provincial officials, including representatives from provincial environmental departments, Health Canada, Natural Resources Canada and Transport Canada. The Advisory Group was created to provide broader stakeholder participation, including by the automotive and refining industries. Its role was to incorporate the diverse perspectives into the recommendations and to provide technical expertise to the Working Group.

The CCME Process introduced several key dimensions into the sulphur in fuel issue that are important to note:

- A systems perspective resulted in a focus on both improved vehicle emission control technology (including on-board diagnostic and control systems) and the composition and properties of fuel.
- There was a commitment to the best available science and a recognition that scientific opinion varies and uncertainties may remain.
- Economic health benefits were derived using the Air Quality Valuation Model, a spreadsheet tool used to translate changes in ambient concentrations of air pollutants into monetized health impacts; it was the first time this tool had been used in a policy process in Canada.
- Where data were considered insufficient, recommendations were developed in light of the precautionary principle, a principle referred to in Canada's Comprehensive Air Quality Management Framework.

The Working Group commissioned or conducted 22 studies in five subject areas: legislative and administrative framework, benefits, costs, alternatively fuelled vehicles and socio-economic impacts. Several reports were key to the Task Force's final recommendations:

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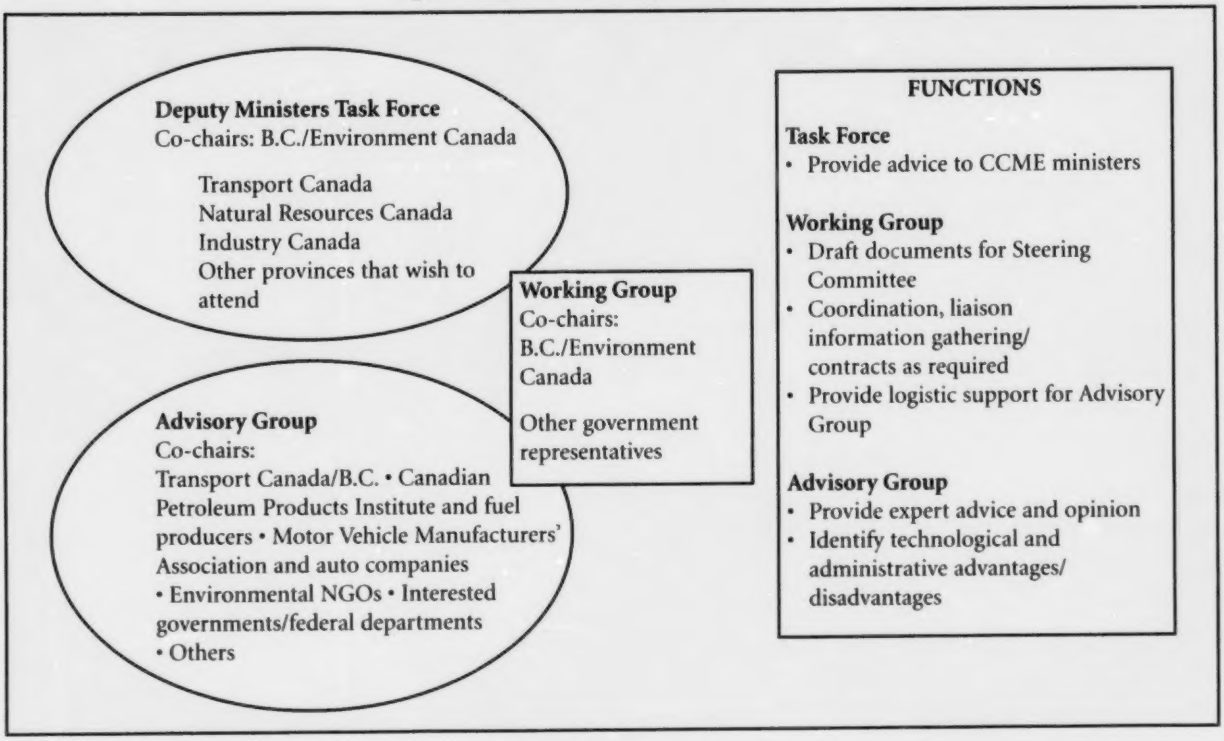
Figure 3. Task Force's Reporting Structure


Deputy Ministers Task Force
Co-chairs: B.C./Environment Canada
Transport Canada
Natural Resources Canada
Industry Canada
Other provinces that wish to attend
Working Group
Co-chairs:
B.C./Environment Canada
Other government representatives
Advisory Group
Co-chairs:
Transport Canada/B.C. • Canadian Petroleum Products Institute and fuel producers • Motor Vehicle Manufacturers' Association and auto companies • Environmental NGOs • Interested governments/federal departments • Others
FUNCTIONS
Task Force
• Provide advice to CCME ministers
Working Group
• Draft documents for Steering Committee
• Coordination, liaison information gathering/ contracts as required
• Provide logistic support for Advisory Group
Advisory Group
• Provide expert advice and opinion
• Identify technological and administrative advantages/ disadvantages

Source: *Final Report of the Task Force on Cleaner Vehicles and Fuels*, October 1995.

1. Supplemental Report 1: Air Quality Modelling (November 3, 1995).
2. Supplemental Report 2: Selected Concentration-Response Functions for Human Health Effects (October 5, 1995).
3. Supplemental Report 3: Selected Economic Evidence of Monetary Valuation of Human Health Effects (October 5, 1995).
4. Supplemental Report 4: Benefits Study Results and Uncertainty Analysis (October 16, 1995).

The Advisory Group vetted the various reports and provided input to the Working Group. This extensive research effort was integral to the CCME Process and to its final output, which was the *Final Report of the Task Force on Cleaner Vehicles and Fuels*. Most notably, this report resulted in two key recommendations (recommendations 5 and 6) to direct further effort on sulphur levels in gasoline and diesel:

Recommendation No. 5: National Standard for Low-Sulphur Diesel recommended that Environment Canada lead in the development and implementation of a regulated national standard for sulphur in on-road diesel of not greater than 500 ppm by October 1, 1997. The recommendation further directed Environment Canada to consider additional information over the duration of the Sulphur Panel Process and to re-evaluate the 500 ppm level if new evidence suggested further action.

Recommendation No. 6: National Standard for Gasoline directed Environment Canada, in consultation with stakeholders and the provinces, to lead the development and implementation of a regulated national standard for gasoline, with the further direction that such a standard for sulphur should represent the lesser quantity of sulphur from the following two process outcomes:

- Process a) would represent a level put forward by the refiners and automotive industry as the level required to meet fuel compatibility issues for Tier I and LEVs; and
- Process b) would represent a level determined by Environment Canada and the stakeholders to be a cost-effective limit taking into account the associated health and environmental benefits. The work already conducted in the CCME Process suggested that the acceptable level was likely to be less than 200 ppm, but that further work was required.

The Task Force report was presented to the CCME and was made public on October 23, 1995. Some participants, largely members of the stakeholder Advisory Group, disagreed with the health impacts and valuation of the health benefits. Since the CCME Process was not consensus-driven, any dissenting views would have been considered but not necessarily reflected in the final recommendations.

While there was some criticism of the CCME Process, Ross White[7], Manager of the Oil, Gas and Energy Branch at Environment Canada, attributed the success of the Sulphur Panel Process, in part, to the carefully drafted wording of the CCME recommendations. White went on to say: "The recommendations gave Environment Canada the direction it needed to proceed quickly in establishing the Sulphur Panel Process." With the Deputy Minister of Environment Canada as co-chair of the CCME Task Force, and the provincial ministers of the environment on-side with the recommendations, support existed at the federal and provincial levels for the Sulphur Panel Process to address sulphur in gasoline.

On-Road Diesel Fuel Regulations Promulgated

Following CCME recommendation 5, Environment Canada proceeded with efforts to regulate on-road diesel sulphur levels. The Sulphur Panel Process's Government Working Group report later stated that "in 1993 the average sulphur level for the total diesel pool in Canada was 1800 ppm. By 1997 the average level was reduced to 1200 ppm," a change that was attributed to a memorandum of understanding between Environment Canada and most domestic refiners.

The Diesel Fuel Regulations were promulgated on February 19, 1997, and in accordance with the CCME directions established a level of 500 ppm for sulphur content in diesel for on-road vehicles. It was acknowledged that the Sulphur Panel Process would further consider the level of sulphur set forth in this regulation, and make additional recommendations based on the results of the fact-finding efforts of the new expert panels, where various diesel sulphur scenarios for on- and off-road diesel would be considered.

Vehicle/Fuels Compatibility Task Group

The CCME Process also identified the importance of fuel compatibility in light of emerging low-emission vehicle technologies (recommendation 6a). While not linked directly to the Sulphur Panel Process, the efforts of this Task Group occurred in parallel to it, and were incorporated in the Government Working Group's final report. The Vehicle/Fuels Compatibility Task Group identified a number of issues including:

- Vehicles operating on higher sulphur gasoline have higher emissions of all regulated pollutants than vehicles operating on lower sulphur gasoline.
- The magnitude of the effects of higher sulphur is variable based on a number of factors, but no system is completely immune to the effects of high sulphur.
- The negative effects of high sulphur on the catalyst, oxygen sensors and on-board diagnostics are reversible using a procedure to increase system temperatures.

- There are limited data on the impacts of sulphur concentration and their reversibility in low-emission vehicles.

Due to the technical information gaps, the Task Group could not determine whether sulphur levels above 80 ppm (the maximum sulphur limit allowed in the most restrictive sulphur scenario examined during the Sulphur Panel Process) would be compatible with low-emission vehicles. This deferred a decision on the regulatory position to the Sulphur Panel Process.

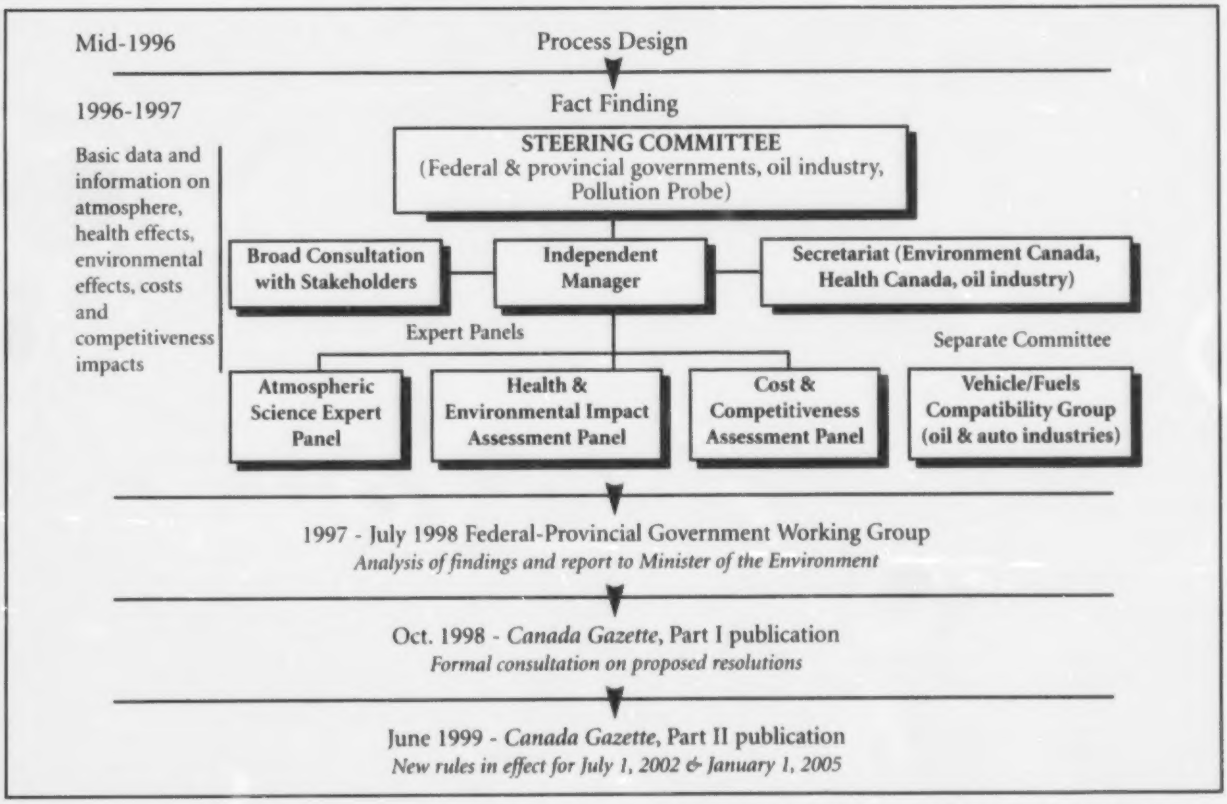
Expert Panel and Government Working Group for Sulphur in Gasoline and Diesel (Sulphur Panel Process)

The CCME Process directed Environment Canada to take the policy process for sulphur in gasoline and diesel to the next stage, determining national standards in consultation with relevant federal, provincial, industry and non-governmental organization (NGO) representatives. The CCME Process had also raised the bar in terms of the complexity of the methodology that was used (i.e., the use of the AQVM to model health impacts). The refiners, represented by the Canadian Petroleum Products Institute (CPPI), approached Environment Canada with some suggestions for a process that would support a more open policy development strategy. The CCPI provided direct input into the process design and provided two-thirds of the funding for the Sulphur Panel Process (see Figure 4).

The Steering Committee

Environment Canada initiated the Sulphur Panel Process based on CCME recommendation 6. The first step was to establish a multipartite steering committee to define the process and

Figure 4. Sulphur Panel Process


Mid-1996
Process Design
1996-1997
Fact Finding
Basic data and information on atmosphere, health effects, environmental effects, costs and competitiveness impacts
STEERING COMMITTEE (Federal & provincial governments, oil industry, Pollution Probe)
Broad Consultation with Stakeholders
Independent Manager
Secretariat (Environment Canada, Health Canada, oil industry)
Expert Panels
Separate Committee
Atmospheric Science Expert Panel
Health & Environmental Impact Assessment Panel
Cost & Competitiveness Assessment Panel
Vehicle/Fuels Compatibility Group (oil & auto industries)
1997 - July 1998 Federal-Provincial Government Working Group
Analysis of findings and report to Minister of the Environment
Oct. 1998 - Canada Gazette, Part I publication
Formal consultation on proposed resolutions
June 1999 - Canada Gazette, Part II publication
New rules in effect for July 1, 2002 & January 1, 2005

Source: *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel*, July 1998.

organizational structure that would carry out the CCME mandate (Task A). The Steering Committee was co-chaired by Environment Canada and Health Canada and included representatives from industry associations, environmental groups and the provinces.

This process comprised three sequential tasks, as described in the Government Working Group's final report:

Task A: Develop a mandate and process for establishing the sulphur levels in gasoline and diesel (performed by the Steering Committee).

Task B: Gather and analyse the necessary data including costs and benefits, environment and human health impacts, etc. (performed by the expert panels).

Task C: Formulate recommendations by government departments based on the findings of the expert panels (performed by the Government Working Group).

The Steering Committee members were involved in approving the selection of the expert panel members. Dr. Rick Burnett, a senior scientist with Health Canada and member of the Health and Environmental Impact Assessment Panel, said that "panel selection was critical to ensuring that the final reports were objective and were the shared opinion of the panellists."[8] The *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel* states: "Panel members were selected based upon their knowledge and expertise in the relevant fields. As well, the Steering Committee made a conscious effort to ensure that the panel membership represented a broad spectrum of views." Ultimately each of the panel members was reviewed and approved by all Steering Committee members.

Kerry Mattila, Vice-President of the Canadian Petroleum Products Institute, noted that while the design that was eventually approved by the Steering Committee was excellent, he added that "the flaw in the process came from unrealistic time frames."[9] Mr. Mattila noted that the Steering Committee quickly moved from an agreement in principle in June 1996 to the first meeting in August, where expert panel deliverables were requested for just after Christmas. Although the timelines for the final reports were eventually extended and the final reports of the expert panels were submitted in summer 1997, Mr. Mattila claims that several leading experts declined to participate in the panels due to the short time frame originally set out.

The Expert Panel Process

The expert panels were tasked with gathering and reporting factual information in three areas of focus:

1. Atmospheric Science Expert Panel — the impacts of vehicle emissions on ambient air concentrations that result from various gasoline and diesel fuel sulphur content scenarios.
2. Health and Environmental Impact Assessment Panel — the effects of the various pollutants on human and environmental health and the valuation of those impacts assigned to the various sulphur scenarios.
3. Cost and Competitiveness Assessment Panel — the cost to Canadian industry and the effects on competitiveness of implementing the various sulphur reduction scenarios.

The expert panels were consensus bodies, and participants were required to debate the research findings to achieve a sign-off of the final report. Each of the expert panels focused primarily on various gasoline and diesel scenarios as the basis for their assessments. Figure 5 describes the six gasoline scenarios and the three diesel scenarios that were presented to the expert panels.

The panels presented their analysis as projected effects from 2001 to the year 2020.

Figure 5. Sulphur Reduction Scenarios

Gasoline Scenarios	Scope	Maximum Annual Refinery Average (ppm)	Maximum per Litre (ppm)
1	*All vehicles	360	420
2	*All vehicles	250	300
3	*All vehicles	200	250
4	*All vehicles	150	200
5	*All vehicles	100	150
6	*All vehicles	30	80
Diesel Scenarios			
1	Off-road vehicles	400	500
2	On-road vehicles	300	350
3	On-road vehicles	50	100

* denotes all gasoline vehicles

Source: *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel*, July 1998.

Each of the expert panels was tasked with a complex fact-finding mission, and each ultimately delivered a consensus document representing the views of the expert professionals (the panel processes are highlighted below). Each panel circulated a draft report to stakeholders for comment. Comments were considered and incorporated into the final report, where appropriate, by the expert panels. The final reports were reviewed by the Steering Committee and released to the stakeholders.

The Atmospheric Science Expert Panel

The *Atmospheric Science Expert Panel Report* estimated the air emission impacts of the nine sulphur in fuel scenarios on seven Canadian cities: Vancouver, Edmonton, Winnipeg, Toronto, Montreal, Saint John and Halifax. Two working groups were formed to generate the following information:

Emissions Group

Estimated:

1. baseline emissions from vehicles;
2. emission reductions expected in the nine scenarios for sulphur in gasoline.

Ambient Air Modelling Group

Estimated:

1. changes in directly emitted particles and gases;
2. secondary aerosol production;
3. effects of reductions on visibility.

Figure 6 is a summary of the Atmospheric Science Panel's findings. These are presented as a range of pollution reduction results for the seven cities studied that are achievable by 2020 in the most restrictive scenarios. The results of the seven-city study were crucial to the Health Panel, which was tasked with translating the reductions in pollutants into avoided health impacts in the same seven cities. These results were accepted by all parties. Considerable attention was paid to describing the uncertainty that arose in the modelling effort. Uncertainties stem from both the emission estimates and the modelling approaches.

The Health and Environmental Impact Assessment Panel

The Health and Environmental Impact Assessment Panel carried out five primary tasks to complete its report:

Figure 6. Sulphur Effects on Air Pollution

Pollutant (species)	**30/80 ppm Sulphur in Gasoline**	**400/500 ppm Off-Road Diesel**	**50/100 ppm On-Road Diesel**
Sulphate (SO_4) (combined primary and secondary) in $\mu g/m^3$	↓0.02-0.38	↓0.02-0.20	↓0.01-0.07
Sulphur Dioxide (SO_2) in parts per billion (ppb)	↓0.35-1.55	↓0.11-1.09	↓0.15-0.46
Particulates (PM2.5) in $\mu g/m^3$	↓0.02-0.32	↓0.02-0.13	↓0.012-0.04
Nitrogen Oxides (NOx) in ppb	↓0.95-3.41	do not apply	do not apply
Carbon Monoxide (CO)	↓9.97-68.3	do not apply	do not apply
Ground-Level Ozone (O_3) in ppb	↓0.005-0.06	do not apply	do not apply
Volatile Organic Compounds (VOCs) in $\mu g/m^3$	↓0.71-4.01	do not apply	do not apply
Visibility	Only perceptible a small fraction of the time	Only perceptible a small fraction of the time	Only perceptible a small fraction of the time

Source: *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel*, July 1998.

1. selecting a suitable index pollutant;
2. identifying the appropriate health and environmental effects;
3. selecting concentration–response relationships from the literature;
4. selecting the most appropriate valuation methodology for monetizing health and environmental impacts;
5. incorporating uncertainties.

The Health and Environmental Impact Assessment Panel conducted their analysis with respect to the same seven Canadian cities that were examined by the Atmospheric Science Expert Panel, and delivered a report that represented a consensus of the panel. The predicted health effects for the various sulphur scenarios are presented in Figure 7.

The Cost and Competitiveness Assessment Panel

The Cost and Competitiveness Assessment Panel commissioned consultants to study two aspects of the issue. The first study reviewed the capital and operations costs for Canadian refineries to adjust to the various sulphur scenarios. The second study reviewed the impacts of the capital and operations cost increases on competitiveness and viability.

The effects of the economic implications (e.g., capital and operations costs) on the competitiveness of Canadian refineries suggested that the more stringent the regulation, the greater the economic impact on the refining industry. The most stringent level, 30 ppm, would result in cost impacts of $1.8 billion in capital expenditures and operations costs of $119 million annually. The report suggested that the economic viability of three to four refineries would be threatened based on the estimated cost impacts.[10]

The economic impacts were not considered uniform across all refineries and provinces. The consultants conducting the research estimated that the potentially vulnerable refineries would be distributed as follows: Prairies/British Columbia, one; Ontario, one to two; Quebec/Atlantic Region, one.

The Panel findings were accepted by all parties. Some additional research was conducted after the release of the Panel's final report to consider new information on industry's ability to recover a higher percentage of costs from customers. This information was included in the Government Working Group's deliberations.

Figure 5. Sulphur Reduction Scenarios

Gasoline Scenarios	Scope	Maximum Annual Refinery Average (ppm)	Maximum per Litre (ppm)
1	*All vehicles	360	420
2	*All vehicles	250	300
3	*All vehicles	200	250
4	*All vehicles	150	200
5	*All vehicles	100	150
6	*All vehicles	30	80
Diesel Scenarios			
1	Off-road vehicles	400	500
2	On-road vehicles	300	350
3	On-road vehicles	50	100

* denotes all gasoline vehicles

Source: *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel*, July 1998.

Each of the expert panels was tasked with a complex fact-finding mission, and each ultimately delivered a consensus document representing the views of the expert professionals (the panel processes are highlighted below). Each panel circulated a draft report to stakeholders for comment. Comments were considered and incorporated into the final report, where appropriate, by the expert panels. The final reports were reviewed by the Steering Committee and released to the stakeholders.

The Atmospheric Science Expert Panel

The *Atmospheric Science Expert Panel Report* estimated the air emission impacts of the nine sulphur in fuel scenarios on seven Canadian cities: Vancouver, Edmonton, Winnipeg, Toronto, Montreal, Saint John and Halifax. Two working groups were formed to generate the following information:

Emissions Group

Estimated:

1. baseline emissions from vehicles;
2. emission reductions expected in the nine scenarios for sulphur in gasoline.

Ambient Air Modelling Group

Estimated:

1. changes in directly emitted particles and gases;
2. secondary aerosol production;
3. effects of reductions on visibility.

Figure 6 is a summary of the Atmospheric Science Panel's findings. These are presented as a range of pollution reduction results for the seven cities studied that are achievable by 2020 in the most restrictive scenarios. The results of the seven-city study were crucial to the Health Panel, which was tasked with translating the reductions in pollutants into avoided health impacts in the same seven cities. These results were accepted by all parties. Considerable attention was paid to describing the uncertainty that arose in the modelling effort. Uncertainties stem from both the emission estimates and the modelling approaches.

The Health and Environmental Impact Assessment Panel

The Health and Environmental Impact Assessment Panel carried out five primary tasks to complete its report:

Figure 6. Sulphur Effects on Air Pollution

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The effects of the economic implications (e.g., capital and operations costs) on the competitiveness of Canadian refineries suggested that the more stringent the regulation, the greater the economic impact on the refining industry. The most stringent level, 30 ppm, would result in cost impacts of $1.8 billion in capital expenditures and operations costs of $119 million annually. The report suggested that the economic viability of three to four refineries would be threatened based on the estimated cost impacts.[10]

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The Panel findings were accepted by all parties. Some additional research was conducted after the release of the Panel's final report to consider new information on industry's ability to recover a higher percentage of costs from customers. This information was included in the Government Working Group's deliberations.

Figure 7. Health Impacts: Avoided outcomes over the entire period of the analysis (2001–2020) by fuel scenario and by specific outcome

AVOIDED EFFECT	Gasoline Scenario						Diesel Scenario		
	1 360 ppm	2 250 ppm	3 200 ppm	4 150 ppm	5 100 ppm	6 30 ppm	1	2	3
Premature Mortality	533	743	895	1020	1160	1352	756	143	318
Chronic Respiratory Disease Cases	1880	2620	3160	3600	4090	4770	2660	503	1120
Respiratory Hospital Admissions	335	466	589	640	728	848	474	90	200
Cardiac Hospital Admissions	272	379	456	520	591	689	385	73	162
Emergency Room Visits	1480	2070	2490	2840	3230	3760	2100	399	887
Asthma Symptom Days	205000	284000	343000	390000	443000	517000	289000	55000	122000
Restricted Activity Days	296000	412000	497000	565000	643000	749000	419000	80000	177000
Acute Respiratory Symptoms	7070000	9850000	11870000	13500000	15400000	17900000	10000000	1900000	4220000
Lower Respiratory Illness (child)	25000	35000	41000	47000	54000	62000	35000	8000	15000

Source: *Health and Environmental Impact Assessment Panel Report*, June 25, 1997, Figures 6 & 7 (revised).

The Government Working Group

The last step of the Sulphur Panel Process was represented by the Government Working Group (GWG) on Sulphur in Gasoline and Diesel Fuel, which was tasked to review the findings of the expert panels. Unlike the steering committee and the expert panels, the GWG's membership consisted solely of federal and provincial representatives (see Figure 4). The Government Working Group had three key tasks:

1. interpreting and integrating the findings of the three expert panels;
2. analysing the findings of the three expert panels and determining the impacts of reducing sulphur levels across the various scenarios;
3. recommending an appropriate level for sulphur in gasoline and diesel and implementation options (e.g., a time frame) to the Minister of the Environment.

In addition to reviewing the findings of the expert panels, the GWG also reviewed the *Vehicle/Fuels Compatibility Task Group Report* (see CCME recommendation 6a) and conducted a cursory review of actions to reduce sulphur in gasoline and diesel in other jurisdictions (a review that was international in scope).

The Government Working Group solicited stakeholder feedback. Following the release of its interim report, the GWG asked stakeholders to submit their views on an appropriate level for sulphur in gasoline and diesel based on the options outlined in the report. They received 14 submissions. The majority of the feedback supported the 30/80 scenario, based largely on the estimated health benefits.[i]

The Government Working Group circulated its final report on April 3, 1998, to over 250 stakeholders. In addition to a written response,

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The Government Working Group circulated its final report on April 3, 1998, to over 250 stakeholders. In addition to a written response, stakeholders were also given the opportunity to support their written submission at a workshop held in Toronto on May 21, 1998. Barry Thomas, Health Canada's representative on the GWG, noted that one presentation in particular seemed to impress the Panel: staff members from "the Montreal Urban Community presented the view that given the option of keeping their refinery or improving local air quality, they would choose the improved air quality."[11]

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[i] A summary of the feedback received from stakeholders is included in section four of the *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel.*

The Government Working Group considered the expert panel reports and stakeholder input. In an effort to compare health benefits with compliance costs, they also considered additional information that extrapolated the health benefits to the entire Canadian population, beyond the 40 percent of Canadians included in the Health Panel's seven-city analysis.[ii] As a result, the GWG determined that the estimated avoided health effects were as follows: 1,352 avoided premature deaths, 58,429 avoided respiratory cases in children, 2,086,511 fewer acute asthma symptom days and a large reduction in other respiratory problems over a 20-year period.

The Government Working Group concluded in its final report that sulphur in off-road diesel fuel required additional fuel volume and sulphur level data for the seven cities studied, as well as for cities of comparable size. Once the data are available, Environment Canada, with key stakeholders, will consider the costs and benefits of further reductions in sulphur levels in off-road diesel fuel.

The GWG also concluded that further reduction in on-road diesel levels below 500 ppm should be given a lower priority than actions to reduce sulphur in gasoline. The recommendation for further study and action may be necessary to protect the health of Canadians and to support any future technical requirements of emerging diesel engines.

At the end of the process, the Government Working Group was unable to reach consensus on a single option or recommendation for a sulphur level in gasoline. In the absence of a consensus, the GWG presented four options:

1. A 30 ppm annual average and 80 ppm maximum level of sulphur in gasoline is mandated in all of Canada effective January 1, 2002.
2. Option 1 is implemented in Quebec and southern Ontario effective January 1, 2002. A 30 ppm annual average and 80 ppm maximum is mandated for the rest of Canada effective January 1, 2005.
3. Southern Ontario is dealt with as in option 2. The Lower Fraser Valley is mandated to the 30/80 ppm level, effective January 1, 2004. A freeze at 1994 levels of sulphur is implemented in the remainder of Canada, pending a decision in the United States.
4. A 150 ppm annual average and a 200 ppm maximum level of sulphur in gasoline is mandated in all of Canada, effective September 1, 2003. If the United States announces a lower level than the 150/200 ppm level, then Canada will implement that decision nationwide.

Each option was analysed and reported as to the percentage of health benefits and percentage of costs to industry that would result.

The work of the Government Working Group concluded at this point. However, the findings of the Health and Environmental Impact Assessment Panel and the GWG's interpretation of those results continued to generate challenges. The Canadian Petroleum Products Institute provided extensive comment on the GWG preliminary report (119 pages).[iii]

While the Canadian Petroleum Products Institute noted that it supported the overall goal of reducing sulphur levels in gasoline, it called into question several key methodological decisions, including the technique for estimating health effects, and the valuation methodology employed. The CPPI also expressed concerns throughout the process about the cumulative effect of uncertainty, which began with the work of the Atmospheric Science Expert Panel report, and ended with the monetization of the predicted health effects as calculated by the Health and Environmental Impact Assessment Panel. A third major area of dissent was how the findings of the Health Panel's seven-city study were extrapolated to estimate the health benefits to the entire Canadian population.

[ii] A complete account of the methodology employed is available in Appendix A of the Government Working Group's final report.

[iii] A summary of the Canadian Petroleum Products Institute's response to Environment Canada is included on pages 38 to 40 in the Government Working Group's final report. A response from the Canadian Vehicle Manufacturers' Association is also included on pages 40 and 41.

The refining industry made its concerns known to the members of the Government Working Group and policy makers within Environment Canada in several ways:

1. using the stakeholder feedback process;
2. commissioning a separate scientific panel (Cantox Process) whose findings challenged the role of sulphur in gasoline, and the ability to draw policy conclusions from findings with such high degrees of uncertainty;
3. aligning itself with federal and provincial departments that were concerned with the methodologies used to develop the cost–benefit analysis and the issues linked to negative industry impacts (e.g., refinery vulnerability to closure).

As Environment Canada began the internal process of selecting the sulphur level and implementation process, all of the factors that had been identified by the Sulphur Panel Process were taken into consideration by policy analysts, legal advisors and other experts within that department.

The disagreements over the extrapolation of the findings of the Health Panel and the debate about the methodologies and tools employed to generate findings represent the fundamental challenge to the Sulphur Panel Process. This challenge may be defined by the existence of two opposing viewpoints: a) the feeling that the expert panel findings represented the best available scientific advice and were a sound basis for regulation, and b) the feeling that the results were too speculative to base a decision on.

Environment Canada Develops the Draft Regulations

Because there was no consensus on a single option to reduce sulphur levels in gasoline, Environment Canada was tasked with the selection of the option that would form the basis of the regulations. This was an internal process that drew on other federal and provincial inputs. Health Canada was a key contributor in supporting the findings of the Health and Environmental Impact Assessment Panel and in addressing challenges that continued to come forward from stakeholders.

Canada Gazette, Parts I and II

Based on the options and rationale outlined in the Government Working Group's final report, and in consultation with various federal and provincial departments, Environment Canada generated the Sulphur in Gasoline Regulations. The regulations, based on modification of several options, introduced an interim national sulphur level of 150/200 ppm (annual average/maximum) for 2002, and targeted the 30/80 level for implementation in 2005. The Minister of the Environment published a copy of the Sulphur in Gasoline Regulations in the *Canada Gazette*, Part I, on October 31, 1998. The *Gazette* process generated a significant volume of feedback from interested parties, which was compiled and released in January 1999.

Responses to the first posting of the Sulphur in Gasoline Regulations were considered by Environment Canada, and following some modifications (largely to the implementation mechanics), the regulations were published in the *Canada Gazette*, Part II, on June 23, 1999. The modifications attempted to address the issues of economic vulnerability that were presented by the refining industry. Specifically, the option to meet a 150 ppm average from mid-July 2002 to December 31, 2004, would provide the industry with more flexibility to undertake a single-step reduction to 30 ppm.

Sulphur in Fuel Endnotes

1 Natural Resources Canada. *Canada's Energy Outlook*. April 1997.

2 *Report to the Canadian Council of Ministers of the Environment by the CCME Task Force on Cleaner Vehicles and Fuels*. October 23, 1995.

3 Department of the Environment. "Sulphur in Gasoline Regulations." *Canada Gazette*, Part II, June 23, 1999.

4 *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel*. July 14, 1998.

5 Department of the Environment. "Sulphur in Gasoline Regulations."

6 Transport Canada and Environment Canada. *A Plan to Identify and Assess Emission Reduction Opportunities from Transportation, Industrial Engines and Motor Fuels*, May 1989.

7 White, Ross. Manager, Oil, Gas and Energy Branch, Environment Canada. Personal interview. August 12, 1999.

8 Burnett, Rick. Acting Chief, Environmental Health Surveillance, Health Canada. Personal interview. August 3, 1999.

9 Matilla, Kerry. Vice-President, Canadian Petroleum Products Institute. Personal interview. August 9, 1999.

10 *Final Report of the Government Working Group on Sulphur in Gasoline and Diesel Fuel.*

11 Thomas, Barry. Senior Scientific Advisor, Bureau of Chemical Hazards, Environmental Health Directorate, Health Canada. Personal interview. August 10, 1999.

Methylcyclopentadienyl Manganese Tricarbonyl (MMT) Case Study

C

Introduction

Background on the Substance

Since tetraethyl lead began to be phased out in the 1970s, Canada has looked for alternative fuel additives to boost the octane rating of fuels and to ensure clean and continuous burning without damage to the engine. MMT, or methylcyclopentadienyl manganese tricarbonyl, has been used in Canada since 1976 to raise the octane rating of unleaded gasoline. In an internal combustion engine, MMT burns to form various carbon compounds (e.g., hydrocarbons and carbon monoxide) and manganese compounds. Some of these compounds have been shown to be toxic in high concentrations and are suspected of health effects at low concentrations, particularly if they are inhaled. However, manganese at low concentrations is an essential element of the diet.

MMT has been the subject of repeated regulatory reviews in both Canada and the United States. These reviews have focused on the effects of MMT on automobiles, as well as potential public health implications. The U.S. Environmental Protection Agency (EPA) has sought to restrict the use of MMT in unleaded gasoline in the United States through the *Clean Air Act*, citing concerns over health and environmental effects. It has consistently turned down applications by the manufacturer of MMT, Ethyl Corporation, for a waiver to allow Ethyl to market the substance as a new additive in unleaded gasoline (MMT was already on the market in other formulations such as leaded gas and jet fuel).

In the most recent of its reviews, the U.S. EPA concluded that MMT does not cause or contribute to the failure of emission control devices or systems. However, the EPA denied the waiver, again expressing concerns over health effects, and requested that additional health research be conducted on MMT before it is allowed in unleaded gasoline. The EPA was supported by the non-governmental organization (NGO) community, led by the Environmental Defense Fund, and also by the automotive industry, which repeatedly expressed concerns about impacts on sensitive on-board diagnostic instruments in automobiles.

Ethyl subsequently appealed the EPA's decision to the U.S. Court of Appeals. The Court ruled that the EPA did not have legal authority to deny Ethyl the right to market MMT, since the EPA could only consider emission factors, not health effects, under the specific clause for the waiver. Consequently, MMT is currently a legal fuel additive in the United States. However, the Environmental Defense Fund is leading a public campaign against MMT and has threatened to publicly disclose companies that use it. Very few U.S. oil companies use MMT, although some have reportedly expressed interest in its use.

The first health effects study on MMT by Health and Welfare Canada (now Health Canada), in about 1977–78, was carried out in anticipation of the importation of MMT and its use as an anti-knock additive in gasoline.[1] The study assessed the literature at that time and found no significant health effects at the concentrations of manganese expected in the ambient environment. Between 1978 and 1995, Health Canada carried out several more health assessments that arrived at similar conclusions.

In 1996, Environment Canada announced that it would control MMT under a trade bill, *Bill C-29* (the *Manganese-based Fuel Additive Act*), claiming that MMT can impair the on-board diagnostics and air pollution control devices of vehicles and thus indirectly harm the health of Canadians.[2] This bill was strongly supported by 21 domestic and offshore automobile manufacturers. However, the bill was rescinded after a panel formed under the Agreement on Internal Trade (AIT) found that it was inconsistent with the federal government's obligations under the AIT. It was also noted that the effects on on-board emission control and diagnostic systems had not been demonstrated.

The following concerns have been raised during the last 25 years regarding the use of MMT as a fuel additive:

- concern that, since manganese causes neurological effects in occupationally exposed people, there could also be health effects in people exposed to ambient levels of the substance;
- concern that the health effects of manganese may be similar to those associated with tetraethyl lead, since both substances are organometallic compounds used in a similar fashion;
- concern that potential damage to catalytic converters, as well as to the on-board diagnostics (or monitoring devices) of automobiles, could lead to environmental impacts;
- concern regarding the economic impacts if MMT does significantly affect the functioning of pollution monitoring equipment on automobiles (leading to higher vehicle prices);
- concern about the economic impacts on the refining industry if MMT use is prohibited;
- concern about potential interprovincial trade restrictions with implications for the North American Free Trade Agreement (NAFTA);
- concern over the appropriate use of risk assessments and the use of the precautionary principle as a policy tool;
- concern over the information gaps (especially in the health arena); these gaps hamper decision making to protect human health and the environment;
- uncertainty over the lack of definitive evidence regarding the effects of MMT on emissions of nitrogen oxides (NOx), hydrocarbons, and carbon monoxide and dioxide and the subsequent effects on levels of greenhouse gases (some evidence suggests that MMT increases certain pollutant emissions, while other studies indicate that MMT decreases them).

Overview of the Decision-Making Process

There are three distinct procedural issues in the history of controlling MMT in Canada that need to be addressed:

- the process and the decisions leading to the control and phasing out of MMT in Canada;
- the decision to use trade legislation to control MMT;
- the tribunal or panel process under the Agreement on Internal Trade that voted against the legislation, leading to the withdrawal of the bill.

In Canada, several reviews of health effects and risk assessments by Health Canada have found no evidence of significant health effects associated specifically with exposure to manganese from exhaust emissions. MMT itself was not considered a "priority substance"[i] under the *Canadian Environmental Protection Act* (CEPA), and therefore was not assessed under CEPA's priority substance program. Meanwhile, the U.S. EPA, as well as several Canadian researchers and the Environmental Defense Fund, have disagreed with some of Health Canada's conclusions and identified the need for additional research to assess the health effects of inhaled manganese.

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[i] CEPA has established a process to identify substances for a "priority substances list" and made a commitment to assess these for toxicity. MMT was not listed as a priority substance, nor was it designated as "toxic" under CEPA.

There have been a number of government efforts to ban or control MMT in Canada, although Environment Canada did not use CEPA to control the substance (probably because Health Canada's risk assessments had found insufficient evidence of health effects and Environment Canada was not able to demonstrate sufficient air pollution effects). In 1996, for example, Environment Canada introduced *Bill C-29* to control the interprovincial trade and import of MMT, citing potential indirect health effects caused by increased air pollutants from malfunctioning vehicle pollution control systems (such as sensitive on-board diagnostic systems). The bill was supported by the automotive industry but not by the petroleum industry, which uses MMT as an economical additive to formulate a clean-burning fuel. Ethyl Corporation, meanwhile, has consistently maintained that MMT is "safe" at the concentrations used.

Subsequent to the passing of *Bill C-29*, Ethyl Corporation launched a challenge to the legislation in Ontario court as well as under the NAFTA. Several provincial governments also objected under the Agreement on Internal Trade, constituting a panel that found the federal government did not have the right to control internal trade in such a manner. In light of the AIT ruling, the government withdrew the trade bill and settled with Ethyl Corporation. The issue never reached a NAFTA trade panel.

Today, the scientific community remains divided over the interpretation of the health and environmental effects data on MMT. Also, the automotive industry and the petroleum industry are at loggerheads about the use of this fuel additive. Some Canadian politicians have expressed a desire to control MMT for a number of health and environmental reasons. For example, the first Liberal Red Book contained a commitment to replace MMT with what the Liberals claimed were "safer" alternatives such as ethanol, and several members of Parliament introduced private member's bills to ban the substance. However, Canadian regulators have felt that they do not have sufficient justification to control MMT under the *Canadian Environmental Protection Act.*

Chronology

The history of MMT in Canada is intertwined with developments in the United States. Figure 1 shows key milestones representing the major steps in both countries.

Issues of Process Surrounding MMT

Over the years, the issue of MMT took on a progressively higher profile, pitting the automotive industry against the petroleum industry in Canada, causing controversy over the risk assessment carried out by Canadian and U.S. experts, and dividing the scientific community in Canada. It also led to significantly different policies and programs in Canada than in the United States: in Canada, MMT has been used for over 20 years, whereas in the United States it was banned as an additive for unleaded fuel until 1995. After a ruling by the U.S. Court of Appeals ordering the EPA to permit its use, MMT became a legal additive for unleaded fuel in the United States.[ii]

In addition to outlining the debate surrounding MMT, this case study also briefly examines how the MMT issue tested the interprovincial trade bill, and provided a foretaste of the dispute resolution component of the NAFTA. As well, the study helps to examine Canada's use of what could possibly be considered a more "precautionary" approach to policy formulation as an adjunct to more traditional risk assessment methods.

[ii] Only a small percentage of gasoline in the U.S. currently contains MMT.

Figure 1. Chronology

1976	MMT is used in Canada as an octane booster to replace tetraethyl lead in gasoline.
1977	The use of MMT is banned in unleaded gasoline in California and controlled under the *U.S. Clean Air Act* for use in unleaded gasoline throughout the United States.
1978	Health Canada evaluates MMT as an alternative to lead gasoline additive and finds no significant health effects.
1970–90	Canada phases out lead in gasoline.
1978 & 1981	Ethyl Corporation applies for waivers from the U.S. EPA restriction on the use of MMT in unleaded gasoline. Both waivers are denied based on concerns over increased hydrocarbon emissions and effects on emission control systems.
1985–86	The Royal Commission on Lead also examines MMT. It finds no significant health effects.
1990	Ethyl files a third MMT waiver application with the U.S. EPA.
1992	The U.S. EPA denies the Ethyl waiver application based on concerns that the use of MMT might increase hydrocarbon emissions.
1993	The U.S. Court of Appeals overturns the U.S. EPA decision to ban MMT, stating that the EPA could only ban the substance if there were a failure of the catalyst or if hydrocarbon emissions increased. However, the EPA upholds the ban, citing suspected neurological effects.
1993	A private member's bill is introduced in Parliament to ban MMT. The bill is not passed.
1993	The U.S. EPA determines that the use of MMT does not cause or contribute to the failure of emission control devices or systems.
1994	Health Canada undertakes independent studies of MMT but concludes that there are no significant health effects.
1994	The Cleaner Vehicles Task Force, under the Canadian Council of Ministers of the Environment, starts to examine MMT but abandons the attempt upon introduction of *Bill C-94*.
1995	Sheila Copps, Minister of the Environment, introduces *Bill C-94* to control the interprovincial movement of MMT. This bill dies on the order paper.
1995	The U.S. Court of Appeals rules that the U.S. EPA exceeded its authority. MMT becomes a legal fuel additive in the United States.
1996–97	*Bill C-94* is reintroduced as *Bill C-29* by Copps' successor, Sergio Marchi, and is passed by Parliament. The Senate Standing Committee on Energy, Environment and Natural Resources cites the precautionary principle.
1996	The Environmental Defense Fund in the United States launches a public campaign to limit the use of MMT and approaches oil refiners, threatening to make public the names of those that may be using MMT.
1996	The Canadian Petroleum Products Institute commissions a study on vehicle monitoring systems and finds no negative effects from MMT.
1997	A panel is established under the Canadian Agreement on Internal Trade to examine *Bill C-29*. The panel finds that the MMT ban of *Bill C-29* is inconsistent with the AIT.
1998	The Canadian government withdraws *Bill C-29* and settles with Ethyl Corporation before Ethyl's challenge can be heard under the NAFTA.
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The research for this case study identified a number of process issues with respect to MMT. First, it was often unclear how decisions were made by the government. Environment Canada, for example, wanted to control MMT, but the rationale for this decision was not clear: was it the existence of sufficient evidence of health and environmental effects? Or a suspicion of environmental effects? Or were there other pressures, as some interviewees implied? To what extent was the *Canadian Environmental Protection Act* considered? Why use a trade bill, especially an interprovincial bill, to control MMT? Is CEPA being used to its best advantage when two ministers need to agree in order to use its regulatory powers?

Figure 1. Chronology

1976	MMT is used in Canada as an octane booster to replace tetraethyl lead in gasoline.
1977	The use of MMT is banned in unleaded gasoline in California and controlled under the *U.S. Clean Air Act* for use in unleaded gasoline throughout the United States.
1978	Health Canada evaluates MMT as an alternative to lead gasoline additive and finds no significant health effects.
1970–90	Canada phases out lead in gasoline.
1978 & 1981	Ethyl Corporation applies for waivers from the U.S. EPA restriction on the use of MMT in unleaded gasoline. Both waivers are denied based on concerns over increased hydrocarbon emissions and effects on emission control systems.
1985–86	The Royal Commission on Lead also examines MMT. It finds no significant health effects.
1990	Ethyl files a third MMT waiver application with the U.S. EPA.
1992	The U.S. EPA denies the Ethyl waiver application based on concerns that the use of MMT might increase hydrocarbon emissions.
1993	The U.S. Court of Appeals overturns the U.S. EPA decision to ban MMT, stating that the EPA could only ban the substance if there were a failure of the catalyst or if hydrocarbon emissions increased. However, the EPA upholds the ban, citing suspected neurological effects.
1993	A private member's bill is introduced in Parliament to ban MMT. The bill is not passed.
1993	The U.S. EPA determines that the use of MMT does not cause or contribute to the failure of emission control devices or systems.
1994	Health Canada undertakes independent studies of MMT but concludes that there are no significant health effects.
1994	The Cleaner Vehicles Task Force, under the Canadian Council of Ministers of the Environment, starts to examine MMT but abandons the attempt upon introduction of *Bill C-94*.
1995	Sheila Copps, Minister of the Environment, introduces *Bill C-94* to control the interprovincial movement of MMT. This bill dies on the order paper.
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Other questions included the following: was Canadian scientific or technical information accessible and used appropriately by the assessing agencies? Is risk assessment a reasonable process to predict the potential impacts of a toxic compound? Is there room for the precautionary principle, and how should it be used? Knowing that information gaps are inevitable, how much information is needed to make decisions? Were trade and economic impacts considered and weighed appropriately?

Many people interviewed for this study expressed opinions about what hampers due and transparent process:

- lobbying of politicians;
- decisions behind closed doors, as happened with the Agreement on Internal Trade panel;
- entrenched commitments without sufficient data to support them;
- preconceived perceptions of impacts, rather than dispassionate analysis of issues;
- distrust among NGOs, industry and governments.

Discussions with several interviewees yielded the following suggestions for improving policy decisions. There is a need for:

- transparent decision making by governments (clearer delineation of the pros and cons), including decisions made under the AIT panel process;
- increased stakeholder consultation, perhaps mandated by regulations;
- more dialogue between various researchers both within Canada and internationally;
- better and clearer communication of what is known and what is not known, especially to political entities and to interested stakeholders;
- a better link between the production of scientific information and policy setting.

Account of the Development, Decision-Making and Implementation Process for MMT Regulations in Canada and the United States

History in Canada

In Canada, alkyl lead compounds, anti-knock agents and octane boosters were phased out between 1970 and December 1990. This phase-out resulted in increased use of MMT for raising the octane ratings of unleaded gasoline (MMT provides only a limited amount of octane to Canadian gasoline, and other additives and refining are also necessary). During this period in the United States, octane levels were achieved by changing refinery production to increase the aromatic content and/or branched chain hydrocarbon percentage, as well as by using oxygenated fuels (e.g., ethanol, methanol, methyl tertiary-butyl ether [MTBE]).

In 1978, in anticipation of the phasing out of lead additives in Canadian gasoline, Health Canada carried out a review of the possible human health implications of the expected increase in the use of MMT, particularly the effects on ambient air quality due to MMT-derived manganese. The department concluded that there was "no evidence at present [based on data available in 1978] to indicate that expected ambient manganese concentrations would constitute a hazard to human health."

The question of MMT and manganese was re-examined in 1985–86 by the Royal Commission on Lead in the Environment, as part of its deliberations on lead substitutes. The Commission arrived at a similar conclusion,[3] finding that there were no significant health effects from manganese at ambient exposures.

In 1987 and 1988, Health Canada commissioned two independent studies. One examined the then-current toxicity database for MMT (i.e., animal studies) and manganese,[4] and the other completed an exposure assessment, including uptake of manganese, for various segments of the Canadian population.[5] The conclusions of both studies agreed with those of the earlier reports.

In 1994, Health Canada undertook an independent risk assessment for the Canadian situation, focusing on new epidemiological studies (both Canadian and international) and Canadian exposure data. It concluded that the levels of airborne respirable manganese[iii] to which the population in large Canadian urban centres is exposed are below the benchmark air level of 0.11μg Mn/m^3 at which no adverse health risks are expected (this level is within the range of the most recently set U.S. benchmark of 0.09–2.0 μg Mn/m^3). This assessment included infants, the elderly and the occupationally exposed.

Overall, by 1994, there was general agreement between Canada and the United States on the derivation of the reference concentrations,[iv] but disagreement on the exposure estimations.[6] The Americans based their estimations on exposure models from California (where MMT was allowed in small quantities in leaded gasoline), while Health Canada used actual Canadian data.[7]

Also in 1994, the Canadian Council of Ministers of the Environment (CCME)'s Task Force on Cleaner Vehicles and Fuels started to examine the issue of MMT, but abandoned its review in 1995 when the MMT trade legislation was introduced.

This legislation, introduced by the Minister of the Environment, Sheila Copps, was *Bill C-94*, a bill to control the use of MMT in Canada by prohibiting anyone from importing MMT into Canada or transporting it across provincial boundaries. The bill died on the order paper, but was reintroduced in 1996 by the new Minister of the Environment, Sergio Marchi, as *Bill C-29*. This bill was passed and became law in 1997. During its examination of *Bill C-29*, the Senate Standing Committee on Energy, Environment and Natural Resources cited the precautionary principle as a prudent course of action for the control of MMT.

Prior to the passage of *Bill C-29*, the Canadian Petroleum Products Institute proposed an expert panel process similar to the one that eventually took place for sulphur in fuel. They also offered to reduce MMT voluntarily, but only subject to the withdrawal of *Bill C-29* from the order paper.[8] In 1996, the Institute also commissioned a study on vehicle monitoring systems that found no evidence of any significant effects on vehicles associated with MMT.

Meanwhile, the auto industry in North America consistently supported the ban on MMT, initially claiming that manganese affects catalytic converters, and later that it affects the vehicles' on-board diagnostics. The main driver for the industry position was a new on-board diagnostic (OBD 2) system, which might be affected by the combustion products of MMT. The industry was and is reluctant to develop different technology for different jurisdictions. Prior to the passing of *Bill C-29*, the Canadian Vehicle Manufacturers' Association submitted confidential data to the Minister of the Environment on the impact of doing this on the economy.

In October 1997, after *Bill C-29* become law, a panel was established under the Canadian Agreement on Internal Trade. The panel found that the MMT ban was inconsistent with the Agreement on Internal Trade (which was set up to facilitate interprovincial trade) and ruled against the MMT trade legislation.

In 1998, the Canadian government withdrew the trade legislation and settled with Ethyl Corporation before Ethyl's complaint could be heard under Chapter 11 of the NAFTA.

Throughout this period, a number of health toxicology and epidemiology researchers in

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[iii] It should be noted that "respirable manganese" is defined by particle size, since only a certain range of sizes of manganese compounds will reach the lungs and cause toxic effects.

[iv] In simplified terms, the so-called reference concentration (or level) is a U.S.-coined expression to define the concentration of airborne respirable manganese that is considered to pose a negligible risk.

Canada and the United States consistently expressed concerns about the potential long-term health effects of manganese from tailpipe emissions, about the information gaps and about the possible build-up of manganese in the environment in a way similar to lead.[9] These researchers also did not fully agree with Health Canada's assessment of the risks.

Parallels have been drawn between tetraethyl lead and MMT, since they are both fuel additives that are organometallic compounds. Also, like lead and many other compounds, MMT can accumulate in the body. One of the key differences is that lead is not essential at any level, while manganese is an essential element in the diet at trace concentrations. It should also be noted that far smaller amounts of MMT than tetraethyl lead are used in gasoline.

History in the United States

Since Canada's environment and economy are tied so closely to those of the United States, it is useful to understand what happened to MMT in that jurisdiction, particularly since events were radically different there. Most of the discussion below was derived from a U.S. document made available by the U.S. EPA, as well as discussions with staff of the EPA.[10]

The U.S. EPA fought hard to get rid of tetraethyl lead (often referred to simply as lead) from the environment. Although MMT, like tetraethyl lead, is an organometallic fuel additive, EPA literature from the 1970s[11] reveals that manganese was then considered a reasonably safe alternative to lead. The current concern over manganese-based fuel additives on the part of some researchers evolved only gradually as data pointing to potential health effects from manganese exposure came to light. Today, manganese-based fuel additives are on the EPA's list of potentially toxic air pollutants.

In 1977, MMT was banned for use in unleaded fuel in California, because it was determined that MMT increased hydrocarbon emissions and might block the type of catalytic converter then in use for unleaded fuel. On September 15, 1978, as a result of the 1977 *Clean Air Act* amendments, MMT was prohibited from use in all U.S. unleaded gasoline. However, MMT remained in use in leaded gasoline until its eventual phase-out in 1995. In 1977, Ethyl Corporation, the principal North American manufacturer of MMT, first applied to the U.S. EPA for a waiver of the prohibition on including new additives (including MMT) in American unleaded gasoline. This application and a succeeding one in 1981 were refused on the basis that Ethyl failed to demonstrate that the use of MMT would not cause or contribute to emission control system failures.

A third application by Ethyl Corporation in 1990 was withdrawn due to a technical dispute with the U.S. EPA over some test results, and was resubmitted in July 1991. In January 1992, the EPA again ruled that MMT should not be allowed in fuel, as it had led to substantially increased hydrocarbon emissions in tests by the Ford Motor Company. These emissions could lead to catalyst failure after long use (over 50,000 miles). At the time, the EPA was unaware that Ford had employed an unreported fuel efficiency strategy on the vehicles used in these tests. The EPA subsequently alleged that this strategy causes an increase in several pollutant emissions. As part of a 1998 consent order settling the issue with the EPA, Ford was required to purchase and permanently retire substantial emissions credits.[12] This potentially complicates the interpretation of the results of the MMT emissions tests on Ford vehicles.

In 1993, a U.S. Court of Appeals accepted a petition for review of the 1992 denial decision, and after Ethyl Corporation submitted additional extensive emissions data to resolve earlier questions and conflicts, the U.S. EPA agreed to reconsider the decision denying MMT additives by November 1993. Based on these new data, the EPA ultimately concluded that MMT did not contribute significantly to increases in hydrocarbon emissions or failures of catalysts after extended service based on available data. The main question that then remained was whether the use of MMT would present an unacceptable health risk to Americans. The EPA therefore came to an agreement with Ethyl to continue to review the health risks.

In 1993, the U.S. EPA also agreed to review the basis for the new reference concentration for manganese, taking into account comments received from Ethyl Corporation and others, as well as some additional original data.[13] The EPA carried out its new risk assessment, using modelled exposure projections for the greater Los Angeles area (where small amounts of MMT were allowed in leaded gasoline), as well as some actual measurements of manganese in tailpipe emissions. Canadian ambient and personal exposure monitoring data were available to EPA researchers, but were rejected for various reasons. On July 13, 1994, the EPA announced that it would deny Ethyl Corporation's waiver application on the grounds that there remained unresolved concerns regarding the health impact of manganese emissions produced by MMT use.

In 1995, Ethyl Corporation again appealed the decision to ban MMT. This time, the U.S. Court of Appeals ruled that the EPA had exceeded its authority, since under the *Clean Air Act* clause 211 (f)(4) cited by the EPA, the agency can only act based on evidence about the emission control system, and cannot make judgments based on health. In 1995, as a result of a U.S. District Court order, the EPA granted the waiver to Ethyl Corporation, and MMT became a legal fuel additive for use in conventional unleaded gasoline in the United States. The EPA could have appealed to the Supreme Court but decided not to.[14]

As a result of the promulgation of the health effects testing regulations for fuels and fuel additives (59 FR 33092, June 27, 1994), Ethyl Corporation will be required to conduct health effects testing for MMT. In February 1999, the U.S. EPA proposed alternative tier 2 health effects testing requirements for MMT that the Ethyl Corporation will be required to undertake once they are finalized. The purpose of these testing requirements is to help characterize the potential health risks posed by manganese tailpipe emissions.

Other Actions in the United States

During the 1990s, a number of public hearings took place in the United States that received extensive testimony in connection with the 1990 waiver application by Ethyl Corporation.

In March 1991, the U.S. EPA sponsored an international workshop to discuss research requirements for clearer delineation and quantification of possible exposure and adverse health effects due to manganese from automotive sources (Health Canada participated in these discussions). The main concern of the EPA and some other scientists was that if MMT were used in all gasoline, ambient air manganese levels could rise sufficiently to cause central nervous system damage with Parkinson's-like symptoms. Such effects had been observed among workers whose occupations exposed them to high levels of manganese.

In 1996, the Environmental Defense Fund, a U.S.-based environmental group and longtime proponent of MMT control, led a coalition of NGOs in the United States to advocate a ban on MMT use. They launched a public campaign and sent letters to petroleum refiners. They also supported the trade ban in Canada. These organizations were and are concerned about the potential health effects of MMT and the gaps in knowledge about the health effects.

Health Effects of MMT

Much of the debate over MMT centres on whether there are any potential health effects from the manganese associated with auto emissions — it is acknowledged, however, that the major source of manganese in the environment is from steel mills and other sources. Much of the concern stems from the possible parallels between lead and manganese. However, this analogy is fraught with controversy. Manganese, like lead, can cause neurotoxic effects (although at different and lower concentrations than lead). Another critical difference between the two metals is that manganese at low levels is an essential nutrient in the diet, while lead is toxic at all levels. As Karen Florini of the Environmental Defense Fund said: "We need to know when Dr. Jekyll becomes Mr. Hyde."

The issues surrounding the health effects of MMT can be summarized as follows:

- What are the "safe" or "no effect" levels (or what should be the reference concentrations) of respirable manganese?
- What are the actual exposures that are associated with manganese emissions? Are they above or below the reference concentrations?
- Have there been any recent studies to determine the existence of any sensitive populations that are at risk?
- Is there a build-up in the environment, and therefore can we expect a problem in the long run?
- Can we isolate the effects of ambient manganese from auto emissions, as opposed to other sources such as the natural or occupational environment?

The toxicity of manganese varies according to the route of exposure. Manganese has low toxicity by ingestion at typical exposure levels, probably due in part to a low rate of absorption from the gastrointestinal tract and other physiological mechanisms. Manganese is considered to be an essential trace element in the diet and is required for certain enzymes that help maintain normal functioning of the central nervous system and other body organs. However, since the early 1800s, manganese at concentrations greater than 5 mg/m^3 has been known to be toxic to workers who inhale it.[v] Manganism is characterized by various neurological and movement disorders, and bears a general resemblance to Parkinson's disease (e.g., difficulties with the fine control of some movements and lack of facial expression). Other effects include respiratory effects and reproductive dysfunction.

Various epidemiological studies of male workers exposed to manganese at levels below the current American Conference of Governmental Industrial Hygienists threshold limit value (5 mg/m^3)[15] have also shown neuro-behavioural, reproductive and respiratory effects (using objective testing methods as well as workers' self-reported symptoms on questionnaires). The existence of some limited evidence from an epidemiological study of school children has also raised concern about pulmonary function effects in relation to lower-level manganese exposure. Inhaled manganese appears to be more toxic than ingested manganese.[16]

The available evidence is inadequate to determine whether manganese is carcinogenic, and some reports suggest that it may even be protective against cancer. Based on this mixed but insufficient evidence, the U.S. EPA has determined that manganese is not classifiable as a human carcinogen and has focused on the potential for chronic non-cancer effects.

Because of the known neurotoxic effects of manganese at occupational levels and previous concerns with lead, Health Canada reviewed MMT in 1978 and, as mentioned earlier, concluded that there was "no evidence at present to indicate that expected ambient manganese concentrations would constitute a hazard to human health." A similar conclusion was reached by the Royal Commission on Lead in the Environment in 1986, as well as by two independent studies commissioned by Health Canada.[17]

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[v] It should be noted that manganese occupational studies predominantly involved men.

Most researchers agree on the effects of manganese exposure described above. Where dissension occurs is in the area of the so-called reference concentration and the levels of exposure.

The U.S. EPA's health assessments have been based on the reference concentration, which is defined as "an estimate of a continuous inhalation exposure level for the human population (including sensitive sub-populations) that is likely to be without appreciable risk of deleterious non-cancer effects during a lifetime." The resulting reference concentration of 0.4 μg Mn/m^3 was used for the earlier EPA risk assessment.[18] In 1993, after re-evaluating existing data and considering new data, the reference concentration was revised to 0.05 mg/m^3. Later, in 1994, researchers in the United States and Canada agreed that the reference concentration should be revised upward to between 0.09 mg/m^3 and 0.2 mg/m^3. Canada has determined a reference concentration that is within this range, that is, 0.11mg/m^3. The World Health Organization considers the reference concentration should be about 0.15mg/m^3, while Ethyl Corporation has recommended a reference concentration of 3.0 μg Mn/m^3 based on different models.

Exposure Assessments

There is still considerable debate over the quality of exposure assessment data. According to the U.S. Federal Register:

> Limited data have been available by which to estimate potential personal manganese exposure levels likely to be caused by the use of MMT as an additive in unleaded gasoline. For example, after the completion of the EPA's 1990 exposure assessment for manganese (US Environmental Protection Agency, 1990), Ethyl Corporation provided the EPA with a report of a personal monitoring study as part of Ethyl Corporation's re-submittal of a waiver application for MMT. The study focused on 6 taxi drivers and 17 office workers in Toronto, Ontario, where the maximum allowable MMT concentration in gasoline is 0.062 g Mn/gal (however, in the Toronto study, the actual concentration was reported as 0.039 g Mn/gal). The US EPA considered the Toronto data to develop a revised manganese exposure assessment. The result was an estimate that 4% of the general public might be exposed to manganese at levels greater than the 0.09 $\mu g/m^3$ reference concentration, although this estimate had an undetermined amount of uncertainty due to the inadequacies of the available data.[19]

The study of Toronto ambient data, therefore, was not considered sufficient to influence the EPA's risk assessment of MMT.

Canadian and U.S. government agencies also disagreed on the relationship between vehicular traffic, MMT use and manganese exposure. The U.S. Federal Register of August 17, 1994, states:

> Since the 1991 US EPA assessment, additional personal exposure studies have been completed in Montreal and Toronto ("Re-evaluation of Inhalation Health Risks Associated with Methylcyclopentadienyl Manganese Tricarbonyl (MMT) in Gasoline"[20]). Based on these studies, the US EPA concluded that there is a general relationship between personal exposure levels of manganese and proximity to vehicular emissions of combusted MMT. Thus, populations living near high traffic-volume areas such as inner cities and expressways would probably tend to experience higher manganese exposure levels caused by MMT usage.

This relationship was not found to be significant in the Health Canada risk assessment of 1994. In fact, that risk assessment found that the highest exposures to airborne manganese are near industrial sources of manganese emissions. According to the assessment:

> No correlation was evident between levels of ambient respirable (PM 10 or PM 2.5) manganese and MMT sales or use in unleaded gasoline, whether examined by geographical area or by season, in spite of the substantial changes in MMT use that have occurred. City size, traffic density and vehicle-related activities are consistently associated with elevated ambient levels of respirable manganese, suggesting that some vehicle-related factors are contributing to manganese exposure, possibly unrelated to direct vehicular emissions."[21]

The U.S. EPA also considered that earlier Canadian exposure studies had significant limitations due to "fundamental differences in the sampling procedures" as well as to issues linked to the "consistency of the data",[22] and did not use them in its exposure estimations. Health Canada, on the other hand, used extensive monitoring data from Canada and elsewhere to establish its risk assessment model. Basically, however, both the U.S. and the Canadian regulatory agencies had the same set of data available and there was general agreement on the reference concentrations. According to Health Canada's 1994 assessment of MMT, "current levels of airborne respirable manganese to which the populations in large Canadian urban centres are exposed, are below the benchmark air level at which no adverse health risks are expected. This assessment includes infants, the elderly and those more heavily exposed than average because of their occupation or their proximity to roads."[23]

The main difference between the data assessments of Health Canada and the U.S. EPA was as follows: Health Canada relied upon an exposure database that was developed over 20 years of MMT use, contained information on ambient manganese levels in urban areas in Canada, tracked known variations in MMT usage, and used some direct measurements of exposure, as well as estimates of total exposure from all sources (air, water and food). The department found no direct link between MMT exposure and health effects. In contrast, the U.S. EPA chose to rely on a set of measurements made in California where MMT was used in leaded fuel. The EPA extrapolated these data to unleaded fuel and predicted personal exposures to manganese. This model showed that some populations might be at risk from exposures in excess of the reference levels.

Discussion of Health Effects

Many researchers are concerned about the possible build-up of manganese in the environment and are planning exposure and epidemiological studies on manganese emissions from motor vehicles. The Environmental Defense Fund has advised both the United States and Canada of the need to do more pharmacokinetic[vi] and neurological studies on manganese.

To date, there is controversy over the findings of Health Canada's risk assessment specialists. There is also a possible "disconnect" between Canadian university-based research and the risk assessment by Health Canada: a number of people interviewed for this case study suggested that some Canadian data may have been available that Health Canada was either not aware of or chose not to use.[24]

Some of the risk-related controversy stems from the use of different risk models. The use of different models and safety factors will affect the risk calculations, and toxicologists do not agree on a generic risk model. The same exposure concentration might be considered unsafe with a very conservative model but safe with another model. The issue of different models is also evident when examining the different risk analyses obtained by Ethyl Corporation and the U.S. EPA. Another issue is the uncertainty due to the lack of adequate data. Any key data gaps will need to be filled if a valid decision is to be made. However, most data sets have many data gaps, and most decisions are based on educated guesses in addition to current data. Safety is almost impossible to prove. One needs only a single negative fact to disprove safety. In its 1994 assessment study, Health Canada recognized the information gaps and strongly recommended further studies of health effects as well as exposure monitoring (see further discussions in the next section on environmental effects).

[vi] "Pharmacokinetics" roughly means the study of the effects and the movement of a substance in biological systems.

According to researchers such as U.S. toxicologist Dr. Ellen Silbergeld of the University of Maryland Medical School, "we need to consider an ecological perspective" of manganese. In Dr. Silbergeld's view, "we need to understand the long-term cycling of manganese in the environment and the total and long-term accumulation. Eventually manganese will build up in the environment as did lead."[25] Dr. Silbergeld also pointed out that Canada can do very little until Health Canada re-evaluates the health issues and finds a negative health impact. Until then, she does not see any basis for Canadians to expect to ban or control MMT.

Environmental Issues

There are two vehicle-related environmental concerns relating to the use of MMT as a fuel additive: effects on catalytic converters and effects on on-board diagnostic equipment.

The potential concern over catalytic converters is that MMT will "gum up" the system and so increase harmful emissions, such as hydrocarbons. The potential concern over on-board diagnostics is that the control equipment may not function properly and may not properly indicate that the vehicle is emitting excess amounts of air pollutants.

In both cases, there would be indirect environmental health effects due to increased air pollution. Also, if air pollution control equipment does not function properly or if the monitoring is disconnected, this may affect the automobile warranties.

Such environmental issues have been raised by the U.S. EPA and Canadian researchers since the 1970s; however, no significant environmental effects have been substantiated by any study. In fact, there are indications that the use of MMT may occasion a modest lowering of NOx emissions. Some studies indicate that hydrocarbon emissions increase, but the U.S. EPA has recently concluded that the use of MMT does not significantly affect hydrocarbon emissions.

A 1994 statement by Carol Browner in the U.S. Federal Register reads as follows:

> I recognize that there are some benefits that will be likely to accrue from approval of MMT use. In addition to the obvious economic benefits associated with reductions in petroleum use and in fuel prices, there might also be some favourable health and environmental effects. It is probable that, if MMT use were to result in reduced NOx emissions from motor vehicles, this would be accompanied by some site-specific decreases in ozone formation.[26]

In spite of these positive environmental effects, Browner did not approve the use of MMT as an additive to unleaded gasoline, citing potential health concerns and information gaps.[vii]

Ethyl Corporation, on the other hand, continues to claim that removing manganese would actually harm the environment since it improves the performance of the gasoline. The company claims to have data that show 20 percent cuts in certain automobile pollutant emissions and that "removing MMT would be like adding another 500 000 cars on the road."[27]

[vii] Under the *U.S. Clean Air Act*, 211-f-4, the EPA needs to consider waiver applications: first it must determine whether an applicant has met its burden of demonstrating that a fuel does not cause or contribute to a failure to meet regulated emission standards. Second it has further discretionary activity in considering other factors. On November 30, 1993, the EPA found that Ethyl Corporation met the first part of the waiver, but used the second part to refuse the waiver. However, under this part of the act, the EPA cannot cite health effects. That is why the EPA's decision was overturned in the Court of Appeals.

The automobile industry has expressed concerns regarding the impact of manganese deposits on expensive on-board diagnostic equipment and on catalytic converters. Data were apparently submitted to Environment Canada, but some of these were not made available to the public, even under the *Access to Information Act*, with Environment Canada citing commercial confidentiality.[28] Documentation exists to show that General Motors was seriously considering disconnecting the sensors that would show whether the catalytic converters were malfunctioning, because of fears that manganese would interfere with the sensors: on February 17, 1995, the President of General Motors Canada, Maureen Kempston Darkes, wrote to the Minister of the Environment, Sheila Copps: "It is with deep regret that I must inform you of the decision we have made to disconnect the (emission system) warning lights on our products for the 1996 model year."[29]

The Canadian Petroleum Products Institute (CPPI) and oil companies claim that MMT is an effective and inexpensive additive that causes no significant environmental or health effects. Some refiners argue that without MMT, they may have to spend an additional $69 million a year to refine petroleum to meet the octane requirements. According to the CPPI, the Canadian petroleum industry is significantly different from its U.S. counterpart, which has different oil sources and has traditionally used different methods to meet fuel emission requirements. The difference is partly due to different legislation in the two countries.

In order to resolve the on-board diagnostics issue with the automobile industry, the CPPI offered to go to a neutral, independent panel such as the Royal Society of Canada's Commission on Lead in the Environment. However, the automobile industry had no incentive to participate once the MMT trade legislation was introduced in 1996, since this bill was going to meet their concerns.[30]

Both Health Canada and Environment Canada recommend more monitoring for manganese, since all the sources of this element in the environment are not known.

In its 1994 assessment of MMT, Health Canada said:

> Because it is not known at this time what the sources of this manganese are, more work is required to identify the sources of manganese, by means of more precise and current emissions inventory data along with source apportionment studies.
>
> Additional ambient air monitoring is required in cities where major manganese-emitting industries are located. Data are required on the chemical speciation, particle size distribution of respirable manganese, and on the population distribution of personal exposure.
>
> It is recommended that additional ambient air monitoring for MMT itself be conducted, due to the substantial increase in MMT use since previous sampling (1979). Specifically, the levels of MMT at gasoline retail outlets and at street level in urban centres are required.[31]

According to Vic Shantora, Environment Canada's Director General of Toxics Pollution Prevention, Environment Canada carried out emissions testing of a number of automobiles in the 1980s.[32] It studied the oxygen sensors of some cars but was unable to substantiate the claims of the automotive industry that these sensors were being fouled up due to the presence of MMT in gasoline. Environment Canada also studied the economic effects of the use of MMT. The goal of the study was to get an independent estimate of the cost of taking MMT out of gasoline if it turned out that the operation of three-way catalytic converters and related equipment was being compromised by MMT. Since Environment Canada could not confirm that emission control equipment was being adversely affected, no further work related to the MMT phase-out was carried out at that time.

As vehicle emission standards in the United States toughened, there was a move to integrate the Canadian and U.S. markets, and this led to the need to harmonize fuel additives as well. The automotive industry is reportedly conducting a $10 million test program in the United States "in order to obtain a definitive answer on their position" on impacts on vehicles.[33]

MMT Substitutes

The use of ethanol as an alternative fuel additive presents various environmental concerns. Ethanol is currently used as a fuel as well as a replacement for anti-knock additives such as MMT, and a number of Canadian companies sell ethanol-blended gasoline (up to 10 percent) that can be used in vehicles without any changes to the vehicle engine. Up to 9 percent of Canadian sales include ethanol blends. There are some environmental concerns over alcohol as well, including the possible emission of compounds such as aldehydes. The risks and the benefits of alcohol need to be viewed from the perspective of its whole life cycle, from generation (fermentation of grain) to end use as a fuel.

Trade Issues

For the last 20 years there has been an ongoing battle between two key players in the Canadian economy, the auto industry and the fuel industry, with the first wanting to ban MMT and the second wanting to keep it in commerce. The vehicle manufacturers claimed economic and health effects if MMT use was going to be allowed, with the petroleum industry claiming the same if it was removed from commerce.

Bill C- 94 and Bill C-29

In 1994, vehicle manufacturers met with the Minister of Environment, Sheila Copps, to inform her that "they would raise prices by $3000 per vehicle, void parts of their warranties, or close down some Canadian manufacturing units" if MMT were kept as a gasoline additive."[34]

In 1995, Minister Copps introduced a bill to ban MMT, citing environmental concerns and the availability of cleaner alternatives. However, *Bill C-94* died on the order paper. Subsequently, the new Minister of Environment, Sergio Marchi, reintroduced the bill on April 22, 1996. The purpose of the bill was to reduce adverse impacts on human health and the environment by controlling emissions of MMT. The bill would achieve its purpose by restricting interprovincial movement of MMT.

Minister Marchi noted at the time of the bill's reintroduction that a properly functioning car emits fewer harmful emissions, which could reduce both environmental and health effects. The Minister claimed that *Bill C-29* would ensure "MMT-free fuel which will enable the emission monitoring equipment to operate as these systems were designed" and that "any increase in warranty costs due to negative impacts on emission control systems will be borne by the Canadian consumer." The backgrounder to the press release announcing *Bill C-29* noted that "the (Health Canada) study did not address the increase in tailpipe emissions resulting from malfunctioning emissions control systems."[35]

In addition to the automotive industry's interest in ending the use of MMT as a fuel additive, there were a number of other drivers for this initiative:

- It was specifically noted in the Agricultural Policy Paper that this was a Red Book commitment and that ethanol is a potential replacement for MMT.[36]
- The government had expressed the need to harmonize with U.S. initiatives.[37]
- Two members of Parliament, Ralph Ferguson and Clifford Lincoln, had raised concerns over health and environmental effects.

After *Bill C-29* was passed in 1997, Canada started to restrict MMT under the *Manganese-based Fuel Additives Act.*

In 1998, the governments of Alberta, Nova Scotia, Quebec and Saskatchewan challenged *Bill C-29* as a restriction of interprovincial trade, and a dispute settlement panel was established under the Agreement on Internal Trade. This panel was considered somewhat analogous to the one under the NAFTA. The AIT panel found the MMT restrictions to be inconsistent with the federal government's obligations under the AIT. The panel also noted that the ban was based on representations by the automobile industry, which maintained that there were adverse effects to the on-board diagnostics. However, the Environment Canada news release of July 20, 1998 announcing the withdrawal of the bill also noted that current scientific information failed to demonstrate that MMT causes such a malfunction.[38]

At the same time, Ethyl Corporation challenged Canada's right to restrict the trade in MMT under the NAFTA. But that challenge never reached the NAFTA arena because of the withdrawal of *Bill C-29* and Environment Canada's out-of-court settlement with Ethyl Corporation for $13 million.[39] This was considered a "reasonable cost and lost profit" by Ethyl Corporation.

Clifford Lincoln expressed serious concern over the panel process of the Agreement on Internal Trade, stating that its deliberations were behind closed doors and the decision was final and could not be challenged. He was also concerned by the membership of the panel: the federal government was given only a single vote on the panel, in his opinion biasing the proceedings against the federal position.[40]

Summary of Analysis

This case study examined the complex issues around the use of MMT in Canada, including the health, environmental and economic effects. Today, MMT is still a controversial fuel additive. It is important to understand how the decisions for its control were made to ensure that Canadians' health and the environment as well as the Canadian economy are protected.

To reiterate, the policy decisions could have been improved with:

- transparent decision making by governments (clearer delineation of the pros and cons), including under the AIT panel process;
- increased stakeholder consultation, perhaps mandated by regulations;
- more dialogue between various researchers both within Canada and internationally;
- better and clearer communication of what is known and not known, especially to political entities and to interested stakeholders;
- a better link between the production of scientific information and policy setting;
- careful definition of the precautionary principle and examples of its application.

MMT Endnotes

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Revalor-H Case Study

Introduction

Background on the Substance

This case study describes an emerging public policy debate that involves Revalor-H — a blend of estradiol-17ß (a natural steroid hormone) and trenbolone acetate (a synthetic steroid compound) — as well as a host of additional hormone-based products used to promote growth in beef cattle. Revalor-H became the focus of media attention in Canada when, in an unusual move, several scientists working for Health Canada's Bureau of Veterinary Drugs (BVD) publicly expressed concern about the safety of the compound.[1] It is worth noting that other beef growth-promoting hormones with similar compositions were already approved for use in Canada.

The Revalor-H approval followed on the heels of a public critique of the BVD's drug approval process for Bovine Growth Hormone (also referred to as BGH, Bovine Somatotrophin and rBST). Unlike beef growth-promoting hormones, which are used to increase meat production, Bovine Growth Hormone is a genetically engineered protein hormone used in dairy cattle to increase milk production. The scientists also publicly expressed their concerns about the risk to human health posed by the use of Bovine Growth Hormone. However, the reason the substance was not approved for use in Canada was due to concerns over animal rather than human safety.

As a result of the public disclosure of the Health Canada scientists' concerns regarding both Revalor-H and Bovine Growth Hormone, and the extensive media coverage of the issue, Health Canada's process for evaluating and assessing hormones used in beef production is now a subject of public debate.[2]

Many beef-producing countries, including Canada and the United States, use hormone implants as growth promoters to increase the production of meat. Several naturally occurring hormones (including testosterone, progesterone and estradiol-17ß) and synthetic hormones (trenbolone acetate, zeranol and melengestrol acetate) have been used to increase muscle tissue growth (i.e., meat production) by supplementing natural hormone levels, a practice that has been widespread in North America since the 1960s.

In Canada, hormones are assessed and approved for use in beef production based on their safety and efficacy in converting feed and producing weight gain. According to Richard Reynolds-Hale of Hoechst Canada Ltd., "improvements in daily weight gain fall within a range of 5 to 15 percent."[3] Mr. Reynolds-Hale added that "improved feed efficiency of 5 to 10 percent (amount of feed per pound of weight gained) has two additional environmental benefits: decreased effluent and land use reductions for feed production." The use of growth promoters in beef production represents a sizeable competitive advantage for an industry with narrow profit margins, and in some cases is considered necessary for survival.

The European Union (EU) banned the use of hormones as beef growth promoters in 1988 (effective January 1, 1989) over concerns for human and animal safety and subsequently blocked the importation of beef from countries that allow this use. The EU's ban has been disputed both by Canada and the United States.

The trade dispute has increased public awareness as both sides of the dispute have relayed their views on the safety of these compounds in the press.

Both in Canada and abroad, the controversy surrounding the use of hormones as beef growth promoters is rooted in concerns over the safety of these products in food production. However, the EU trade issue can also be viewed as a broader example of public and political debate between 1) those who view the ban as a response to concerns over the safety of hormones used as growth promoters and 2) those who view the EU's position as veiled trade protectionism. The debate is influenced by a complex interplay of factors involving cultural differences, globalization, health scares (e.g., Bovine Spongiform Encephalopathy [BSE], also known as Mad Cow disease, and E. coli), economics, risk communication, secrecy, distrust, trade and politics — all of which affect opinions, decisions, behaviour, processes and ultimately health policies related to hormones used as beef growth promoters.

Several key factors affecting the debate are important to note at the outset:

- There has been an increase in public concern over food safety in general (e.g., concerns about genetically modified foods).
- Concerns are emerging that growth hormones may be linked to cancer in humans and animals, and potentially to other abnormalities — these concerns have yet to be widely confirmed by research and are the basis of an emerging scientific discourse within the international research community.
- Growing globalization and liberalization of trade is increasing the number and complexity of trade disputes, including those based on national sovereignty issues such as public health and the environment. This highlights the importance of organizations such as the World Trade Organization (WTO) in resolving trade disputes and providing a balance between national interests regarding health and environmental issues and fair trade practice.
- Economic and competitiveness issues (e.g., the availability of production aids to competitors) are assuming greater importance within domestic and foreign markets. Hormones are used as beef growth promoters in the United States — a principal export market and source of competition to Canadian producers.
- The issues surrounding scientific consensus, burden of proof and the precautionary principle have become important factors in the implementation and defence of national public policy.

Overview of the Decision-Making Process

This case study describes several distinct factors that are directly or indirectly contributing to public interest in the debate over the use of hormones as beef growth promoters.

The first factor is the approval process for Revalor-H and, by association, other beef growth promoters previously approved by Health Canada's BVD. This process has come under public scrutiny following challenges by several Bureau scientists, who claimed that Revalor-H may pose a health risk to Canadians based on their interpretation of data from preliminary animal studies. Their concerns were addressed internally by the BVD through a review committee, which recommended approval of Revalor-H.

The extent of public disclosure in situations of scientific discourse and debate relating to policy development is an important issue that begs further exploration. In the absence of such disclosure, the press and the public may come to erroneous conclusions about the degree of risk associated with the use of beef growth-promoting hormones or any other substance under review.

The BVD and other departments that are engaged in safety and risk assessments have operating guidelines that are intended to limit the disclosure of the health and risk assessment debate. Rules governing disclosure are driven by the proprietary nature of some of the information considered by decision makers. They are also influenced by the fact that complete scientific consensus on the interpretation of health and safety data is rare, and there are internal processes in place to review concerns. These processes may be interpreted as secretive by interested and concerned parties. Consequently, it is difficult for the public to judge whether the events leading up to the approval of Revalor-H are a matter of concern or not, and more importantly whether changes are required in the procedures that protect the health of Canadians.

The second factor described in this case study is the ongoing trade dispute between Canada, the United States and the EU, which is preventing the sale of North American beef in the EU market because of the use of growth-promoting hormones. At the heart of the dispute is the disagreement between the EU and the North American countries over what constitutes sound scientific findings and opinion on the health risks associated with the use of hormones in beef production.

This dispute has involved several international bodies, including the WTO, which eventually ruled against the EU ban. Other international bodies are involved through the WTO, because they are responsible for setting international standards and guidelines. Standards for food include the Codex Alimentarius (a food code set up to establish uniform food standards on a global basis), as well as recommendations by the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Joint Expert Committee on Food Additives (JECFA).

Figure 1. Chronology

1958	Synovex H (a combination of 20 mg estradiol benzoate and 200 mg testosterone proprionate) and Synovex S (a combination of 200 mg progesterone and 20 mg estradiol benzoate and tartrazine) are approved for use in Canada.
1962	The Codex Alimentarius Commission is established to implement a joint FAO/WHO food standards program and to create the Codex Alimentarius, a code to establish uniform food standards. These guidelines are often referenced when resolving WTO disputes over food issues.
1973	Ralgo (36 mg zeranol) is approved for use in Canada.
1986	MGA 100 Premix (220 mg of melengestrol acetate per kilogram of Premix) is approved for use in Canada.
1987	The 32nd meeting of the FAO/WHO Joint Expert Committee on Food Additives (JECFA) finds the use of growth-promoting hormones to be safe for consumers in meat and meat products.
1989	As of January 1, the EU bans the use of growth-promoting hormones in livestock.
1994	Revalor-S, a brand name beef hormone implant for steers (a mixture of 24 mg of estradiol and 120 mg of trenbolone acetate), is approved for use in Canada.
1995	Synovex +, a brand name beef hormone implant for steers and heifers (a mixture of 28 mg estradiol benzoate and 200 mg trenbolone acetate), is approved for use in Canada.
1994	The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) is signed on April 15 by WTO members.
1995	The WTO SPS Agreement enters into force on January 1; it allows countries to choose the level of health protection they deem appropriate, but policies must be based on science and not misused as a disguised restriction on trade.
1996	Canada challenges the consistency of the EU ban on beef growth-promoting hormones under the SPS Agreement on the grounds that the ban is not based on scientific evidence.

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1996	Canada challenges the consistency of the EU ban on beef growth-promoting hormones under the SPS Agreement on the grounds that the ban is not based on scientific evidence.

1996	Canada holds formal WTO consultations with the EU regarding the ban on beef growth-promoting hormones in July. The dispute is not resolved, and Canada requests the establishment of the WTO Dispute Settlement Panel. The Panel is established in October.
1997	In August, the WTO Dispute Settlement Panel releases its final report on the EU ban on beef growth-promoting hormones, which concludes that there is no justification for the ban and that the EU is in violation of its WTO obligations.
1997	Revalor-H, a brand name beef hormone implant for heifers (a mixture of 14 mg estradiol and 140 mg trenbolone acetate), is approved for use in Canada.
1998	In September, the EU appeals the panel report on the ban on beef growth-promoting hormones under the WTO dispute settlement procedure.
1998	The WTO Appellate Body releases its report on January 16. The report concludes that the EU is in violation of its WTO obligations because it has failed to justify its ban on six beef growth-promoting hormones by showing, through a scientific risk assessment, that residues from the six hormones in meat pose a health risk to consumers. (The review considered the natural and synthetic hormones, not the trade names under which they are approved in individual countries.)
1998	In February, the Dispute Settlement Body of the WTO adopts the Panel and Appellate Body reports. The EU requests four years to implement the rulings, a request that Canada rejects; the matter is referred to an arbitrator.
1998	The WTO Arbitrator concludes that there is no reason to give the EU more than the standard 15 months to implement the rulings, giving the EU until May 13, 1999, to comply with its WTO obligations. The WTO provided that Canada and the EU could discuss compensation if the EU failed to comply with WTO hearings. If agreement could not be reached on compensation, Canada could request the Dispute Settlement Body to authorize the imposition of retaliatory duties.
1998	The EU initiates preliminary discussions with Canada on compensation, but the two sides do not come to an agreement about the value and nature of compensation owed or product coverage.
1999	On April 17, in anticipation that the EU might not meet the May 13 deadline, the Canadian government publishes a notice in the *Canada Gazette* to request comments on a retaliation proposal to increase tariffs on certain EU products. The notice provides a preliminary list of products from which a final list of products would be selected; tariffs of 100 percent would be imposed on products in the final list. The deadline for comments is May 17.
1999	The EU Scientific Committee on Veterinary measures relating to Public Health (SCVPH) presents a report concluding that a risk to consumers has been identified, with different degrees of conclusive evidence, for all six hormones.[4]
1999	Several scientists from Health Canada's Bureau of Veterinary Drugs present their views on the approval of Revalor-H to the Senate Standing Committee on Agriculture and Forestry.
1999	The EU does not meet the May 13 deadline for implementation of the WTO requirements.
1999	At a June 3 meeting, Canada requests authorization from the WTO Dispute Settlement Body to retaliate against the EU for its continued ban by imposing a 100 percent duty on selected European export products worth C$75 million annually. The EU requests arbitration on the amount of retaliation that Canada is requesting. The United States requests retaliation worth US$202 million.
1999	On July 12, the WTO Arbitrator determines that the value of Canada's nullification or impairment suffered as a result of the EU ban is $11.3 million annually.
1999	Canada resubmits its request to the WTO Dispute Settlement Body on July 26 for authorization to retaliate against the EU and its member states in the amount of $11.3 million annually; authorization is granted.
1999	On July 29, Canada announces the list of products subject to a 100 percent duty beginning on August 1. The final retaliation list is based on comments received in response to the April 17 *Canada Gazette* notice and the value of retaliation established by the WTO Arbitrator. The products affected are all in the meat sector (beef and pork), except for cucumbers and gherkins. The retaliation precludes the EU from exporting its beef to Canada.

The third factor affecting Canadian public interest in the growth hormone issue is the activity of the EU's strong consumer choice lobby. This lobby is influencing the Canadian debate over consumer choice and labelling, a debate that is also taking place with regard to genetically modified foods.

Chronology

To help make sense of the complexity surrounding the debate, the following chronology illustrates the history of the Canadian approval process and the WTO dispute and labelling issues.

Issues of Process Surrounding Revalor-H

Various process-related issues emerged throughout this case study. These relate to:

- **The Generation and Use of Science**. In the process of reviewing the potential health risks associated with beef growth-promoting hormones, different scientists have reached different conclusions. In the absence of clear consensus among reviewing scientists, it is unclear what course of action to take. Other issues that have arisen are linked to 1) how to deal with new concerns that surface after approval of a substance, or that are not accompanied by conclusive scientific data, 2) what type of information is included in the approvals process and 3) whether any original research is possible or necessary.
- **Public Trust in Governmental Processes — The Imperative of Risk Communication**. The safety of food products is of major interest to the Canadian public, which seeks readily available and understandable information on issues such as Revalor-H. The lack of such information, particularly in terms of risk communication, sometimes results in a lack of public trust in governmental processes and heightened concerns about potential health risks. This case study also highlights the increasingly important role of mechanisms to resolve scientific disputes over the interpretation of data used in the approvals process prior to these disputes becoming the basis for public concern, as well as the need to communicate these mechanisms and their outcomes to the public.
- **Transparency in the Policy Process**. As with other substances, many stakeholders have a stake in decisions regarding beef growth-promoting hormones. Through the course of consultations, some respondents expressed the view that the decision-making process was less transparent than it should be. Also linked to transparency is the issue of public trust in governmental processes and the importance of risk communication.
- **Implementation of the Precautionary Principle**. As currently practised in Canada's substance review process, the assessment of health impacts is determined on the basis of principles that can be described as oriented toward the burden of proof. The precautionary principle is under consideration for application in environmental risk management issues, but its application to veterinary drugs assessment is not yet clearly defined. The place of precautionary approaches in current Health Canada BVD assessments and decision making may be present but is not always well defined for stakeholders. The consideration and application of a precautionary approach to assessments and management decision making would likely benefit from communication with stakeholders.
- **Impacts of Globalization on Canadian Policy**. The WTO's decision to rule in favour of Canada and the United States on the EU's ban on imported meat produced with growth hormones highlighted the influence that global trade practices can have on national health and environment policies. Thus, in the 1990s a new factor has entered into domestic policy decisions, namely, the potential consequence of such decisions on Canada's global trading positions.

Account of the Policy Development, Decision-Making and Implementation Process

The chronology in Figure 1 provided an overview of key events and milestones in the debate surrounding the use of beef growth-promoting hormones. This section deals with the multiple dimensions of the Canadian veterinary drug approval process and the WTO dispute over the use of beef growth-promoting hormones.

The discussion has been complicated by the fact that the debate over beef growth-promoting hormones, the approval process at Health Canada, and the WTO trade dispute are ongoing situations. The challenge is to analyse the path to public policy and process while some issues are still being protected by the stakeholders involved.

Potential Risk to Human Health from Beef Growth-Promoting Hormones

The public is becoming increasingly concerned with the issue of food as a possible source of risk to their health. Canada has one of the safest food supplies in the world, yet with increasing world trade in food and several food scares (e.g., European concern about genetically modified organisms, the BSE issue with British beef, and importing countries' concern over lower environmental and food safety standards) there is cause for diligence.

The first question to answer about the use of Revalor-H and other hormonal substances used as beef growth promoters is: what is the health risk associated with the use of these compounds? There are various viewpoints on this issue but all are affected to some extent by the fact that:

- Science is not absolute — knowledge evolves.
- Risks are assessed differently based on national interests and the scope of information considered.
- Risk management decisions based on the precautionary principle rather than complete scientific proof change the policy outcome.

The negative health implications associated with beef growth-promoting hormones are speculative and not well defined. These compounds — several of which have higher concentrations of estradiol or trenbolone than Revalor-H — have been deemed safe in Canada and the United States based on these countries' risk assessment processes, as well as assessments by a peer-reviewed panel of international scientists. Yet concerns over possible links between some growth-promoting hormones and health effects in animals and humans persist in the European scientific community and within Health Canada. The EU's refusal to withdraw the ban on imported meat may be confusing segments of the Canadian public in light of domestic policy allowing for the use of these substances.

The health concerns over beef growth-promoting hormones originate from two sources: the EU's Scientific Committee on Veterinary measures relating to Public Health, and individual scientists within Health Canada's BVD who presented their concerns to the Senate Standing Committee on Agriculture and Forestry.[5] The following is a summary of health concerns that have been expressed by these two sources and the counter viewpoints. All of these comments illustrate the complexity associated with the evaluation of animal studies.

- A BVD scientist evaluating Revalor-H was concerned by findings in three animal studies that were conducted in Europe. These studies reported decreased thymus weight of young calves that were administered Revalor-H. The thymus is an important organ in young animals and children in the maturation of the immune system. If the thymus is being adversely affected, it may be compromising immune response and the ability to fight infection.[6] A differing view within the BVD noted that animals in these studies receive larger doses than normally administered in order to stress the animals and to identify which organs or systems might be vulnerable to damage (the doses administered in this type of study range from three to 40 times the regularly administered amount).

- The same BVD scientist also noted another finding in the European studies: "an increase in uterine weights ... [and] there was fluid found in the lumens of these uteruses.... Therefore, there was an increase in glandular secretor tissue in the uteruses of the test animals.... termed precocious puberty."[7] There was also an observed decrease in the ovarian weight and a proliferation of mammary tissue in the prepubative udders of heifer calves, which is not normal for immature calves. Upon request, further details of these studies were submitted to the BVD so as to support the assessment process. A differing view within the BVD was that these findings were taken from a target animal study where one calf in a test group demonstrated this effect. Also, the increase in mammary tissues and decrease in ovarian weight was considered by the BVD to be consistent with physiological changes corresponding to high hormone doses (10 and 25 times the normal dose) in a heifer population of this age.

- The recent report of the EU's Scientific Committee on Veterinary measures relating to Public Health (SCVPH)[8] drew the following conclusions. It identified a risk to consumers, with different degrees of conclusive evidence for six hormones: "In the case of 17ß-oestradiol... a substantial body of recent evidence (suggests) that it has to be considered as a complete carcinogen, as it exerts both tumour initiating and tumour promoting effects." However, the current state of knowledge did not allow a quantitative estimate of risks due to the other five hormones. For all six hormones, the Committee claimed that "endocrine, developmental, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged" (with prepubertal children being the group of greatest concern). No threshold levels could be defined for any of the six substances.[9] The methods and assumptions used by the scientific panel of the SCVPH were recently critiqued by an independent panel in the United Kingdom, the Sub-Group of the Veterinary Products Committee.[10] This group voiced significant concern over the scientific reasoning in several key areas including consumer exposure and the link between hormonally active residues in meat, cancers, and human development and reproduction.

There is a range of scientific opinion with regard to the findings from the European animal studies described above. Much of the debate is based on whether the findings have any bearing on human health in the context of existing exposure levels stemming from the consumption of meat and meat products. These are questions that may need to be addressed with additional research.

Overall, the above opinions expressed by some Health Canada scientists and the EU contrast with the case presented by the users of beef growth-promoting hormones: that scientific evaluators, review panels and researchers have all officially concluded that the use of beef hormones for growth promotion purposes, a practice taking place in Canada since the 1960s, does not pose health risks to humans. Numerous countries, including Canada and the United States, have approved various hormones and combinations of hormones for use in beef production after rigorous analysis of scientific data. The Codex Alimentarius Commission has reviewed the use of five of the six hormones and come up with standards for their use (the sixth hormone, melengestrol acetate, is scheduled for review by the Codex Commission in early 2000). Finally, the WTO Review Panel has rejected the EU's ban on beef growth-promoting hormones because the EU was unable to substantiate its concerns with scientific evidence proving harm to human health.

Establishing Acceptable Risk

Determining potential health risks often depends on how a country defines its assessment process. Uncertainty itself is one form of risk and may change the conclusions about the health risks posed by a substance (e.g., are long-term exposures analysed? What other external factors are taken into account? Does the scope of information considered go beyond scientific and include ethical considerations?).

The EU's position of choosing "a level of sanitary protection of accepting no or 'zero' additional risk to human health from the residues in meat and meat products of these hormones when used for growth promotion purposes"[11] led the EU to much different conclusions about the use of beef growth-promoting hormones than those of the Canadian and U.S. governmental scientific processes.

Furthermore, some of the interviewees who were opposed to the use of beef growth-promoting hormones in Canada argued that one of the flaws in the review and risk assessment process in Canada and within international trade bodies is that new drugs and substances must be proven to be harmful, rather than proven to be safe. These interviewees also claim that new substances are "rushed to market [without] taking the time to gather ample and independent evidence of safety."[12] The whole basis for the WTO ruling in favour of Canada and the United States, and against the EU, is that the EU was not able to prove to the satisfaction of the scientific review panel that the hormones in question are harmful. For some, it should not be a question of concerned groups needing to prove harm, but of manufacturers needing to prove safety. David Bennett of the Canadian Labour Congress adds that often risk assessments use limited data and conservative assumptions that do not always provide enough evidence to assess harm.[13] Similarly, Jennifer Story of the Council of Canadians states: "We're not saying that beef hormones are definitely harmful."[14] The problem for these interviewees is a lack of evidence of safety.

The Canadian Veterinary Drug Approval Process

The Canadian drug approval process administered by the Bureau of Veterinary Drugs within Health Canada is under increased scrutiny as a result of the Senate hearings into Bovine Growth Hormone (where Revalor-H was discussed as well) and associated media attention. Criticisms of the management of the process exist on both sides of the debate.

One of the key criticisms focuses on what some consider to be Health Canada's non-transparent drug approval process. It is difficult to obtain information about the approval process: data are not easily referenced, and some staff have been directed to cease external communications associated with the approval of Revalor-H (which may further erode the public's trust in the drug approval process). By comparison, when a drug is approved by the U.S. Food and Drug Administration, a press release is issued and a bibliography of background papers is posted on the Internet. Doug Powell, an assistant professor in the Department of Planned Agriculture at the University of Guelph, stated that "it is extremely difficult in Canada to obtain the same information even though it is available through much hard work and perseverance."[15]

Another criticism expressed by several interviewees on both sides of the debate (industry and consumer/environmental groups) was the apparent lack of consistency throughout the approval process. For example, both industry and consumer groups commented on the apparent lack of consistency 1) between the managers and scientific evaluators within the Bureau of Veterinary Drugs; 2) between reviews of similar substances: products with similar compositions to Revalor-H were approved in 1994 (Revalor-S) and 1995 (Synovex +) without the same controversy as Revalor-H (in some cases, previously approved products contained higher doses of hormones); and 3) between individual scientific evaluators reviewing different drugs.

Additional criticism indicated that the process itself is flawed since it relies only on scientific proof, rather than looking at broader issues important to Canadians (such as social, environmental, ethical and economic issues). In essence, several interviewees already concerned about hormones used as beef growth promoters, stated that the precautionary opinions of some scientific evaluators regarding these substances were not adequately weighed during the risk assessment process or in other decisions that formed the basis for approving these substances for use in Canada. This criticism represents an additional challenge for risk assessors and risk managers: what perspectives are missing to make more informed decisions? How does a process become more open and transparent? What processes could be used in place of established models to incorporate different viewpoints that will not cost more money or take more time?

There are also concerns about the fact that corporations pay for the approval process through Health Canada's cost recovery system, and that corporations provide the data and studies for Health Canada's review of their products. This situation is perceived by some as a conflict of interest. While cost recovery systems have been employed in other departments and agencies responsible for public health, the possible perception of industry influence may not be consistent with efforts to become more transparent to the public. In addition, consumer groups believe it is crucial for the government to conduct independent testing and research (i.e., either in-house or independent of industry funding). On the industry side, some representatives indicated that the Canadian approval process is slow and costly, and could act as a disincentive to submit new (possibly improved or beneficial) drugs for approval.

Potential Economic and Competitiveness Impacts

Despite the risks, or perceived risks, what are the benefits of using beef growth-promoting hormones?

- A 5–15 percent increase in the daily weight gain of the cattle. This weight gain is in the form of useable meat.
- A 5–10 percent improvement in feed conversion and efficiency (i.e., reduction in the amount of feed required to gain a pound of weight).
- A 5–10 percent decrease in food requirements (which also results in less effluent). Leaner, more tender beef.
- Beef prices that are 15–20 percent lower than beef produced without the use of hormones.
- Better use of capital.

Some interviewees from the beef industry and from government also cited animal husbandry as a benefit (the animals are easier to handle), although others from the beef industry disputed that assertion.

It is important to note that a drug's efficacy, or its ability to do what it is supposed to do, is a component of the drug's assessment.

Competitiveness Issues

Canadian beef exports account for 53 percent of our beef production, and 85 percent of exported beef goes to the United States. The United States not only uses beef growth-promoting hormones, but also usually has earlier access to new drugs and hormones. This gives their beef producers a competitive edge in an industry with narrow profit margins. Canada is trying to move away from export dependency on the United States and is making major gains in Asia and Mexico (Canadian beef exports are already up 60–70 percent in 1999); however, there is strong competition from other major producers (Australia, New Zealand, Argentina, Uruguay) that have approved the use of beef growth-promoting hormones.

Several countries have yet to adopt the use of growth-promoting hormones. The EU has been the largest and most visible producing market to ban the hormones. In addition, the EU has prevented the import of beef and beef products from countries that use the hormones. There is ongoing concern over the availability of banned substances through the black market, since illegally obtained growth-promoting hormones may not be used in accordance with good veterinary practice (i.e., they may be used at much higher and thereby more dangerous doses).

Larry Campbell of the Canadian Meat Council said the Council "supports using feeding aids and production aids that are officially approved by government authorities as safe and when used according to the manufacturers' instructions."[16] Other industry perspectives are that scientific studies have shown beef growth-promoting hormones to be safe, that many of these hormones are naturally occurring, and that these substances have been used for a long time. They argue that using hormones to promote growth in beef cattle is necessary to compete, particularly with the United States. In addition, they say Canadians want tender, inexpensive meat.

Those who are against using hormones for beef growth promotion suggest that Canada would have a large export opportunity in Europe, and in some specialty markets, if it did not use these hormones. However, a contrary industry view argues that the specialty market is very small. As Larry Sears of the Canada Beef Export Federation points out, "many consumers are switching to more affordable meat products, and the lengthy feeding regime (sometimes greater than 400 days in the case of Kobe beef, for example) makes the beef prohibitively expensive, and doesn't make use of today's modern and efficient feeding practices."[17]

Another element in the debate described by some interviewees is the situation of farmers who for ethical reasons would prefer not to use hormone supplements but are forced to for competitiveness reasons.

The WTO, International Trade and the EU Factor

Canada and the United States view the EU's ban on beef raised using hormonal growth promoters as trade protectionism to protect the European agricultural industry. The EU's stance is that they do not want to accept risk to human health from hormone residues in meat. Since a large component of this case study revolves around the trade dispute, it is necessary to understand the European perspective.

The Krever report, which reviewed the contributing factors in Canada's tainted blood scandal, put forward recommendations for risk managers and policy makers accountable for public health decisions that profoundly changed policy development in some federal and provincial departments. Food crises in Europe have had a similar influence on the behaviour and culture of the EU's approach to food, and have certainly shaped public opinion and thus public pressure on government and industry. The threat of widespread contraction of Creutzfeldt-Jakob disease (the human equivalent of Mad Cow disease) plagued the British government, the British beef industry and consumers in the EU throughout the late 1980s and 1990s. Related health concerns are still on the radar screen of Britons. This issue and other food crises, including E. coli outbreaks, have helped to shape what currently seems to be a highly conservative consumer view.

While Canada's trade stance has been to "show the WTO the science," Europe's position reflects different cultural, social, environmental and health influences.

The European perspective can be summarized as follows:

- The EU has had more than its share of major food scares, which makes it cautious about food issues.
- There appears to be greater sensitivity to and general appreciation of the views of consumer groups and the environmental movement in most parts of Europe than in Canada; for example:

  - In most countries within the EU (Britain is a notable exception), political decisions pass through a "social and economic committee" before going to Parliament; generally these social and economic committees seek to reflect all different aspects of society including consumer concerns, environmental and social concerns, associations, corporations, management and labour, etc. in policy decisions.
  - Union representatives often sit on the boards of directors of their members' companies; they are a part of all decisions on corporate policy, takeovers, marketing strategies, new products, etc.
- Land-use planning and increased agricultural self-sufficiency is also a major concern; for these reasons, farm policies in the EU focus on protecting the family farm and maintaining farmland as farms. The farm industry receives extensive subsidies.
- The EU frequently has a surplus of meat.

For its part, the Canadian government's position is that the EU's ban on beef growth-promoting hormones is a non-tariff trade barrier since it is not based on scientific evidence. The WTO ruled that the EU must compensate Canada to the tune of $11.3 million annually in trade tariffs. (Canada had asked for $75 million annually, arguing that the ban shut Canada out of the EU market at a time when Canada's capacity to export beef had been expanding.)

Criticisms of the WTO rulings include the following:

- The WTO has become an arbiter on national health policies. As expressed by David Bennett of the Canadian Labour Congress, "an international trade body is deciding on national social, environmental and health policies for the world's citizens."[18]
- International trade and investment agreements are lowering worldwide standards to the lowest common denominator, instead of building up better systems. For example, minimum food safety standards (such as those developed by the Codex Alimentarius Commission) have become a maximum that countries are allowed to impose on their citizens or risk trade disputes and retaliation.
- Fundamentally, where public health is concerned, the onus should not be on the public to prove harm but on industry to prove that their product is safe beyond a doubt.
- Due to the precedent set by the WTO ruling, Canada's sovereign right to decide its own health, environmental and social policies could eventually be eroded. The trading system is flawed if international agreements interfere with domestic policy.
- The fact that actions under the WTO and the North American Free Trade Agreement are in line with international law demonstrates that the whole system and approach is based on flawed underlying principles.

Food Labelling and Consumer Choice

Food labelling has been a hotly contested issue in the food industry. Several manufacturers of genetically modified foods, as well as users of beef growth-promoting hormones, have fought against labelling on the grounds that it affects a consumer's choice regardless of whether the risk to health is perceived or real.

Consumer groups have been very active on the pro-labelling front in the EU and in the United States. However, in test cases where labelling the use of beef hormone implants has been tried, the results have been surprising. In the case of Bovine Growth Hormone (rBST), which is used in dairy cattle, consumer polls in the United States had shown that public concern over suspected health effects from rBST was high and that respondents were favourable to paying extra for rBST-free milk. After rBST was introduced in the United States, however, consumer behaviour in the several U.S. states where non-rBST milk was marketed did not reflect the survey responses, and sales of this milk were much lower than predicted.[19]

Concerning labelling, interviewees' opinions ranged from "no special labelling required"[20] to "mandatory labelling where there is substantial public debate and it is clear that the public wants to know and choose."[21] In light of the weight of existing scientific evidence, the cattle and pharmaceutical industries question the validity of labelling. If the risks from the use of the product are not evident, why would industry want to place their business interests at risk and advantage their competitors in the organic meat business?

Some industry interviewees also indicated that the choice already exists since organic beef is available to consumers.

A pharmaceutical industry representative noted that labelling is fine as long as it is not misleading. For example, labelling beef from cattle that are not raised using beef hormone implants for growth promotion as "hormone-free" is erroneous, because all beef, as does most food, contains some naturally occurring hormones. This representative also said that there is more difference in hormone levels between male and female cattle, and even between female cattle depending on what point in their cycle they are slaughtered, than between meat treated and not treated with hormone implants.

Concerns from groups against the use of hormones for beef growth promotion claim that the public's right to know is denied by corporate influence. There is also a concern that focusing on labelling issues is secondary: these products should not be approved in the first place, but if they are, at a bare minimum, they should be labelled.

Labelling offers the opportunity for consumers to select products based on their beliefs and values. However, beef raised without growth-promoting hormone implants is likely to be more expensive (10–15 percent more expensive), reflecting the higher production costs. When consumers approach the meat counter to consider their choice of beef raised with no artificial growth hormones versus the cheaper growth hormone product, the question remains as to how their perception of risk will measure up against higher prices.

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NRTEE's Health, Environment and the Economy Workshop Participants List

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Participants List

January 13 & 14, 2000

Dr. Alan Abelsohn
Family Physician and Chair
Environmental Health Committee, Ontario
College of Family Physicians and,
Member of the Health, Environment and the Economy
Task Force

Mr. Randy Angle
Head, Science and Technology Branch
Environmental Sciences Division
Alberta Environment

Dr. Ian Arnold
Senior Director
Environment, Health and Safety
Canadian Aluminium Association, Alcan

Mr. John Arseneau
Senior Director and Associate Manager
Environmental Affairs Branch
Industry Canada

Mr. Peter Baltais
Environmental Public Policy and Regulatory Affairs
Imperial Oil Products and Chemicals

Dr. Sheela Basrur
Chief Medical Officer
Toronto Public Health, City of Toronto

Dr. David Bates
Department of Health Care and Epidemiology
British Columbia Medical Association

Mr. Jean Bélanger
NRTEE Member, Member of the Health, Environment
and the Economy Task Force

Mr. Edwin Berry
Vice-President
Regulatory Affairs
Canadian Manufacturers of Chemical Specialties

Dr. Rosalie Bertell
President, ACS
International Institute of Concern for Public Health

Mr. David Black
Economist
Economic and Regulatory Affairs
Environment Canada

Ms. JoAnne Buth
Vice-President
Crop Production
Canola Council of Canada

Mr. Patrick Carson
NRTEE Member, Member of the Health, Environment
and the Economy Task Force

Ms. Cindy Christopher
Manager, Public Policy & Regulatory Affairs
Imperial Oil

Mr. R. A. (Bob) Chyc
Crop Protection Institute

Mr. Michael Cloghesy
Président
Centre patronal de l'environnement du Québec

Dr. Katherine Davies
Consultant
Ecosystems Consulting Inc.

Mr. Douglas B. Deacon
NRTEE Member, Member of the Health, Environment
and the Economy Task Force,
Owner
Trailside Café and Adventures

Mr. Bob Dobson
Canadian Cattlemen's Association

Dr. Terry Fenge
Director of Research
Inuit Circumpolar Conference (Canada) Inc.

Dr. Sheila Forsyth
Forsyth Consulting Essentials,
Member of the Health, Environment and the Economy
Task Force

Mr. Luc Fortin
Project Coordinator
Health Protection Branch
Health Canada

Ms. Deborah Frankel-Howard
Senior Advisor
Health Protection Program
Health Canada

Dr. Dorothy Goldin Rosenberg
Ontario Institute for Studies in Education of the
University of Toronto

Mr. Geoffrey Granville
Manager
Toxicology and Material Safety
Shell Canada Limited

Mr. D. Brook Harker
Senior Soil/Water Resource Specialist
Prairie Farm Rehabilitation Administration
Agriculture and Agri-Food Canada

Ms. Fiona Heald
Ministry of Health of Newfoundland and Labrador

Ms. Mary Hegan
Project Manager, Working Group for Public Involvement
Health Protection Branch Transition Team
Health Canada

Ms. Sonja Henneman
Senior Policy Advisor
Environmental Division
Natural Resources Canada

Mr. Robin J. Hill
Project Manager, Science Platform
Health Protection Branch, Transition
Health Canada

Mr. Stephen Hill
PhD Candidate
Environmental Science
Faculty of Environmental Design
University of Calgary

Mr. Bill Jarvis
Director General
Policy Research Directorate
Environment Canada

Mr. Barry Jessiman
Acting Head, Bureau of Chemical Hazards
Air and Waste Section, Environmental Health Directorate
Health Canada

Ms. Jean Jones
Chair, National Health Council
Consumers' Association of Canada

Mr. Claude-André Lachance
Director, Government Affairs
Dow Chemical Canada Inc. and,
Member of the Health, Environment and the Economy Task Force

Ms. Julia Langer
Director
Wildlife Toxicology Program
World Wildlife Fund Canada

Mr. Gordon Lloyd
Vice-President
Technical Affairs
Canadian Chemical Producers' Association

Dr. Douglas Macdonald
Professor
Environmental Studies Program
Innis College, University of Toronto

Ms. Brenda Machin
President
Agricultural Institute of Canada

Mr. Kerry Mattila
Vice-President
Canadian Petroleum Products Institute

Ms. Elizabeth May
NRTEE Co-Chair
Co-Chair, Health, Environment and the Economy Task Force
Executive Director
Sierra Club of Canada

Ms. Barbara McElgunn
Health Policy Officer
Learning Disabilities Association of Canada

Mr. David McGuinty
Executive Director and C.E.O.
National Round Table on the Environment and the Economy

Dr. Donna Mergler
Director, CINBIOSE
Université du Québec à Montréal and,
Member of the Health, Environment and the Economy Task Force

Mr. Jean-Pierre Moisan
Program Manager
Policy Research Directorate
Environment Canada

Mr. Mark Nantais
President
Canadian Vehicle Manufacturers' Association

Ms. Linda Nowlan
Executive Director
West Coast Environmental Law Association

Mr. Ken Ogilvie
NRTEE Member, Member of the Health, Environment and the Economy Task Force
Executive Director
Pollution Probe

Mr. Louis-Marie Poissant
Agronome, M.Sc, Env.
Agent de planification et de programmation socio-sanitaire
Direction de la santé publique
Régie régionale de de la santé et des services sociaux de l'Abitibi-Témiscamingue

Mr. Rod Raphael
Director General, Environmental Health Directorate,
Health Protection Branch
Health Canada and,
Member of the Health, Environment and the Economy Task Force

Mr. George Redling
Assistant Secretary to the Cabinet
Regulatory Affairs and Orders in Council Secretariat
Privy Council Office

Ms. Angela Rickman
Deputy Director
Sierra Club of Canada

Dr. William Ross
Acting Director
Bureau of Biostatistics and Computer Applications
Health Canada and,
Member of the Health, Environment and the Economy
Task Force

Mr. A. Prescott Rowe
Retired Vice-President, Consultant
Ethyl Corporation

Dr. Grant Royan
Technical Services Manager
Hoechst Roussel Vet Canada Inc.

Ms. Sandra Schwartz
Director of Environmental Programs
Canadian Institute of Child Health

Ms. Wendy Sexsmith
Director of Alternative Strategies and
Regulatory Affairs Division
Pest Management Regulatory Agency
Health Canada

Dr. John Shortreed
Director
NERAM / Institute for Risk Research
University of Waterloo

Mr. Jeff Smith
Senior Vice-President
Hill and Knowlton

Dr. Stuart Smith
NRTEE Chair
Co-Chair, Health, Environment and the Economy
Task Force
Chairman, ENSYN Technologies Inc.

Ms. Jane Storey
Faculty of Health Education
University of Dalhousie

Ms. Jean Szkotnicki
President
Canadian Animal Health Institute

Mr. Ross White
Manager
Oil, Gas and Energy Branch
Environment Canada

Mr. Mark Winfield
Director of Research
Canadian Institute for Environmental Law and Policy

Dr. Joseph Zayed
Environnement et Prévention
Médecine du travail et d'hygiène du milieu
Université de Montréal